



# **Sustainability Meeting**

### CHUGAI PHARMACEUTICAL CO., LTD.

13 November, 2024



# Important Reminders



This presentation may include forward-looking statements pertaining to the business and prospects of Chugai Pharmaceutical Co., Ltd. (the "Company"). These statements reflect the Company's current analysis of existing information and trends. Actual results may differ from expectations based on risks and uncertainties that may affect the Company's businesses.

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

# Agenda



**Chugai's Value Creation** Director, Executive Vice President & CFO Iwaaki Taniguchi **Executive Vice President** Supervisory responsibility for Human Resource **Overview of Material Issues Review** Management and ESG Yoshiyuki Yano Vice President In charge of External Affairs Dept. Co-Creation of a Healthcare Ecosystem 03 Naoya Fujihara **Executive Vice President** Supervisory responsibility for PHC Solution, Partnering and Special Mission for CVF Our Challenge for PHC Solutions Tetsuya Yamaguchi



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# Chugai's Value Creation



Director, Executive Vice President & CFO

Iwaaki Taniguchi

## Positioning of the Sustainability Meeting



Each year we plan themes for evolving sustainability. Last year the meeting name changed from "ESG Meeting" to "Sustainability Meeting"

	Previous year ranking Ranking in the pharmaceutical sector		Sustainability issues	Setting of meeting themes	
Start of IBI 21	2019 1st meeting	) –	Clarifying companywide priorities  → Aim to evaluate and identify issues	Overview of ESG     (starting with overall general content)	
	2020 2nd meeting	DJSI 7th place	Aiming to be a progressive ESG company  → Lift performance on issues to global standard	<ul> <li>Strategies and plans for ESG issues (establish themes based on investor interviews)</li> </ul>	
Start of TOP INNOVATOR 1 2030	2021 3rd meeting	DJSI 3rd place	Advancing ESG as a management strategy  → Strengthen response to issues and medium- to long-term initiatives	• ESG as management strategy (set original themes)	
	2022 4th meeting	DJSI 3rd place	Seeking to be a role model  → Responding in anticipation of changes in society	<ul> <li>Evolution of ESG and promotion of dialogue (set themes that contribute to dialogue)</li> </ul>	
	2023 5th meeting	DJSI 1st place	Expand scope to sustainability  → Restructure value creation model	<ul> <li>Growth strategy and sustainability issues (changed name to Sustainability Meeting)</li> </ul>	
Refinement of TOP 1 2030	2024 6th meeting	DJSI 2nd place	Evolution of sustainability management → Materiality update	Share issues from a sustainability perspective, based on materiality revision	

### Sustainability Promotion System - Review of Corporate Management Committees -



Roche Group

Established a new management committee to consolidate functions and enable cross-organizational management to further strengthen sustainability initiatives as a key management issue



# **Basic Policy – Top Innovator**



We have explicitly incorporated our approach to sustainability into our basic management policy and strategy

#### [Basic Management Policy]

Our basic management policy is to lead the way in resolving social issues by placing sustainability at the center of our business activities, creating shared value through our activities with various stakeholders, and develop together with society.

Our mission is to "Dedicate ourselves to adding value by creating and delivering innovative products and services for the medical community and human health around the world." Based on that mission, we will create shared value by realizing **advanced and sustainable patient-centric healthcare** with innovation that we can create.

#### [Vision for Top Innovator 2030]



Expectation from patients all over the world

With world-class drug discovery capabilities, patients around the world expect that "Chugai will surely create new treatments."



Attracting talent and players from around the world

Attract passionate talent from all over the world, and inspire players globally to think they can create something new by partnering with Chugai.



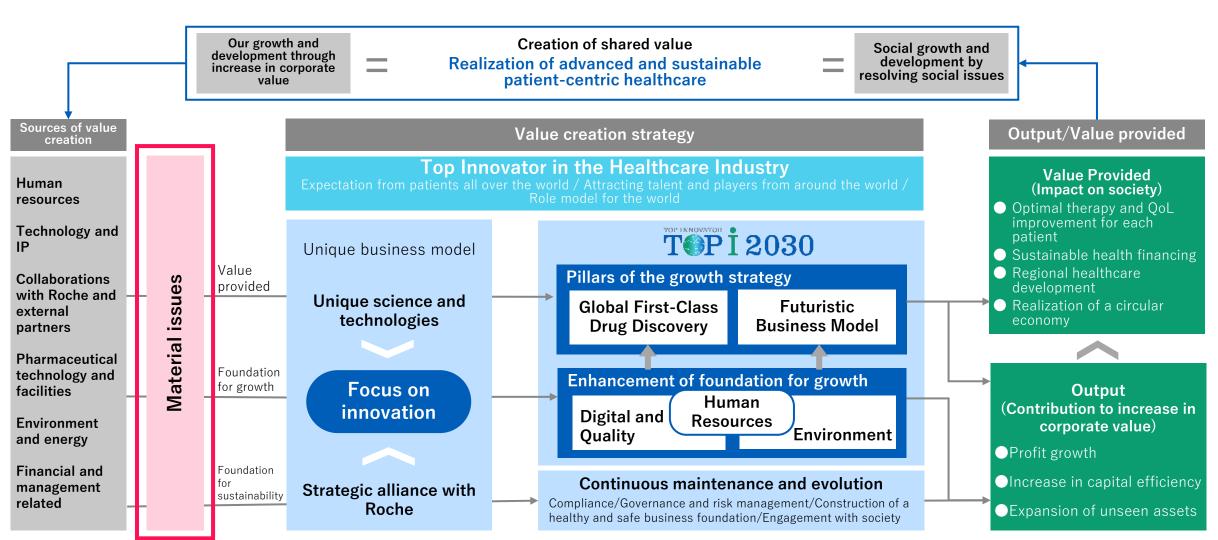
Role model for the world

With sustainability at the heart of its business activities, Chugai will become a global role model as a leader in resolving social issues.

### **Previous Value Creation Model**



A process for creating shared value through a value creation strategy based on materiality



# **Background for Materiality Review/Update**



Set materiality as the axis for value creation and evolve business activities

#### Issues related to materiality

#### Formulation

### Increase accuracy of analysis and evaluation

- Need to include feedback from external stakeholders even more than before
- Clarify opportunities/risks for society and the environment

### Operation

#### Accelerate activity on the front line

- Align activities across the company based on materiality
- Enhance internal recognition of materiality and accelerate activities on the front-line level

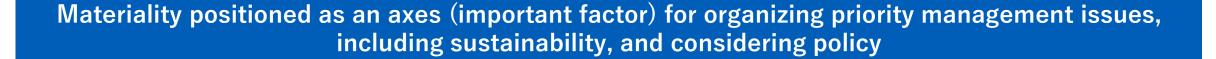
#### **Evaluation and review**

#### Align with strategic KPIs

- Make the relationship between materiality, strategic KPIs, and nonfinancial indicators clearer
- Integrate with ERM and verify annually

#### Changes in society and the capital market

- Information disclosure standards are advancing, such as CSRD (ESRS) and ISSB (SSBJ)
- Increased expectations for disclosure of materiality



### **New Value Creation Model**



A process for creating shared value using materiality as an axes

Creation of shared value Our growth and Social growth and development through Realization of advanced and sustainable development by increase in corporate resolving social issues patient-centric healthcare value Sources of value Material issues Value to be created Value creation strategy creation (Performance) Value Provided Challenges R&D output Top Innovator in the Human (Impact on society) Launch of in-house resources Challenge to create innovative global products Contribution to the **Healthcare Industry** drugs and services, powered by Technology and advancement of society Technology and research infrastructure new ideas and unique strength in through social issue resolution Expectation from patients all over the world Productivity science and technology. Attracting talent and players from around 16 material issues the world Ripple effect of medical value Collaborations Role model for the world with Roche and Co-creation Customer satisfaction Medical value external partners Co-create new value that is truly TOP 12030 **Pharmaceutical** needed, together with Roche and technology and other diverse partners. facilities Pillars of the growth strategy **Environment and** Output Commitments energy **Global First-Futuristic** (Contribution to increase in corporate value) Class Drug Business We lead in solving social issues with Financial and Profit growth Model Discovery a focus on healthcare and act with management • Increase in capital efficiency integrity and forward thinking, toward related realizing a sustainable society. Pursuit of sustainability

# **New Material Issues**



introduced

introduced

in 04

in 03

### Consolidate material issues into 16 items toward creation of shared value

	Previous material issues						
1	Creation of innovative drugs and services	14	Diversity and inclusion (D&I)				
2	Provision of solutions for patients	15	Employee health and safety				
3	Access to healthcare	16	Supply chain management				
4	Fair pricing	17	Corporate governance				
5	Quality assurance and stable supply of products	18	Risk management				
6	Adverse event management	19	Compliance				
7	Safety of clinical trial subjects	20	Fair marketing				
8	Social contribution activities	21	Code of conduct				
9	Disclosure and engagement	22	Fair transactions				
10	Personal information protection and information security	23	Climate change countermeasures (energy, etc.)				
11	Human rights	24	Use of renewable/recycled resources (water, waste, etc.)				
12	Employee job satisfaction	25	Protection of biodiversity (environmental burden mitigation)				
13	Development of employee potential	26	Environmental management system				

*Underlined	sections	indicate	significant	changes	from the	previous	materiality

	New material issues			
1	Creation of innovative drugs and services, powered by unique strength in science and technology			
2	Provision of individualized and optimal solutions to patients			
3	Access to healthcare			
4	Quality assurance and stable supply of products and services			
5	Safety of patients and clinical trial participants			
6	Co-creation of a healthcare ecosystem with society and community			
7	Human capital development			
8	Diversity, <u>equity</u> and inclusion			
9	Employee <u>well-being</u>			
10	Privacy protection and responsible use of digital technology			
11	Respect for human rights			
12	Corporate governance and stakeholder engagement			
13	Ethics, compliance and risk management			
14	Climate change and energy countermeasures			
15	Contribution to circularity and water management			
16	Protection of biodiversity			



# **02**

# **Overview of Material Issues Review**



Executive Vice President Supervisory responsibility for Human Resource Management and ESG

Yoshiyuki Yano

### **Material Issues Reassessment Process**



# Emphasizing detailed analysis and stakeholder perspectives, based on double materiality approach

Process of identifying and finalizing material issues

Step
1

Medium- to long-term environmental analysis and extraction of initial hypothesis

- Analysis of medium- to long-term environment to organize opportunities and
- risks in accordance with the mission statement and basic management policy. Set the principle on double materiality as evaluation axes

### Step 2

Selection of candidate material issues

- Conduct dialogue with outside directors, experts, and investors, etc.
- Compose candidate material issues from the insights and environmental analysis result

## Step **3-1**

Assessment of impact materiality

- Assess the impact on the environment and society due to business activities
- Establish assessment criteria based on "probability × (average score for scale, impact scope, and restorability)" making reference to the concept of CSRD, etc.

# Step **3-2**

Assessment of financial materiality

- Evaluate the impact of environmental and social influences on significant financial effects on business performance and future cash flows
- Using the evaluation criteria of "probability  $\times$  scale," establish scoring standards for scale that align with the company's own risk assessment criteria

#### Step 4

Dialogue with

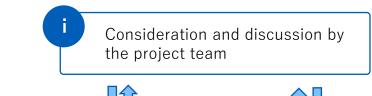
- <u>Conduct dialogue with patient organizations, medical institutions, business</u> <u>partners, academia, social organizations, investors, and others (21 groups in total)</u> regarding the proposed material issues
- · Revise and refine based on the insights obtained

### Step 5

Finalization

- Finalize the material issues, including the associated stories
- Discuss and resolve the final proposal at the Executive Committee and the Board of Directors

Process of discussion and decision-making





Dialogue with stakeholders

21 group in total

Discussion at the Executive Committee



Discussion and resolution at the Board of Directors

Twice in total

# **Materiality Story**



Organize the value creation story along the three themes of Challenge, Co-creation, and Commitments

Material issues	Materiality story			
<ul> <li>Creation of innovative drugs and services, powered by unique strength in science and technology</li> <li>Provision of individualized and optimal solutions to patients</li> <li>Access to healthcare</li> <li>Quality assurance and stable supply of products and services</li> </ul>	Challenges	Challenge to create innovative drugs and services, powered by new ideas and unique strength in science and technology		
<ul> <li>Safety of patients and clinical trial participants</li> <li>Co-creation of a healthcare ecosystem with society and community</li> <li>Human capital development</li> <li>Diversity, equity and inclusion</li> <li>Employee well-being</li> <li>Privacy protection and responsible use of digital technology</li> </ul>	Co-creation	Co-create new value that is truly needed, together with Roche and other diverse partners		
<ul> <li>Respect for human rights</li> <li>Corporate governance and stakeholder engagement</li> <li>Ethics, compliance and risk management</li> <li>Climate change and energy countermeasures</li> <li>Contribution to circularity and water management</li> <li>Protection of biodiversity</li> </ul>	Commitments	We lead in solving social issues with a focus on healthcare and act with integrity and forward thinking, toward realizing a sustainable society		

Shared value

# **Materiality Story Based on Three Themes (1)**



### Challenge of creating innovative drugs and services

Material issues	Materiality story			
<ul> <li>Creation of innovative drugs and services, powered by unique strength in science and technology</li> <li>Provision of individualized and optimal solutions to patients</li> <li>Access to healthcare</li> <li>Quality assurance and stable supply of products and services</li> </ul>	Challenges	Challenge to create innovative drugs and services, powered by new ideas and unique strength in science and technology		
<ul> <li>Safety of patients and clinical trial participants</li> <li>Co-creation of a healthcare ecosystem with society and community</li> <li>Human capital development</li> <li>Diversity, equity and inclusion</li> <li>Employee well-being</li> <li>Privacy protection and responsible use of digital technology</li> </ul>	Co-creation	Co-create new value that is truly needed, together with Roche and other diverse partners		
<ul> <li>Respect for human rights</li> <li>Corporate governance and stakeholder engagement</li> <li>Ethics, compliance and risk management</li> <li>Climate change and energy countermeasures</li> <li>Contribution to circularity and water management</li> <li>Protection of biodiversity</li> </ul>	Commitments	We lead in solving social issues with a focus on healthcare and act with integrity and forward thinking, toward realizing a sustainable society		

#### **Shared value**

# **Materiality Story Based on Three Themes (2)**



### Co-creation of new value with diverse partners

Material issues	Materiality story		
<ul> <li>Creation of innovative drugs and services, powered by unique strength in science and technology</li> <li>Provision of individualized and optimal solutions to patients</li> <li>Access to healthcare</li> <li>Quality assurance and stable supply of products and services</li> </ul>	Challenges	Challenge to create innovative drugs and services, powered by new ideas and unique strength in science and technology	
<ul> <li>Safety of patients and clinical trial participants</li> <li>Co-creation of a healthcare ecosystem with society and community</li> <li>Human capital development</li> <li>Diversity, equity and inclusion</li> <li>Employee well-being</li> <li>Privacy protection and responsible use of digital technology</li> </ul>	Co-creation	Co-create new value that is truly needed, together with Roche and other diverse partners	
<ul> <li>Respect for human rights</li> <li>Corporate governance and stakeholder engagement</li> <li>Ethics, compliance and risk management</li> <li>Climate change and energy countermeasures</li> <li>Contribution to circularity and water management</li> <li>Protection of biodiversity</li> </ul>	Commitments	We lead in solving social issues with a focus on healthcare and act with integrity and forward thinking, toward realizing a sustainable society	

#### **Shared value**

# **Materiality Story Based on Three Themes (3)**



Commitments to working on solutions for social issues centered on healthcare

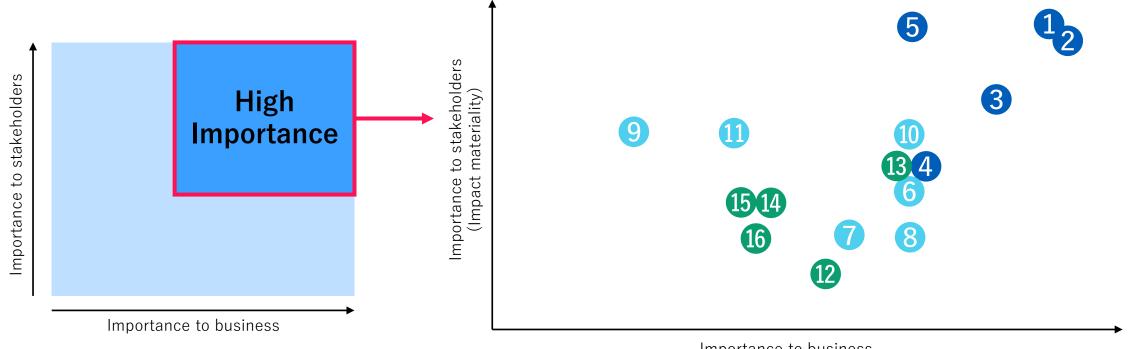
Material issues	Materiality story		
<ul> <li>Creation of innovative drugs and services, powered by unique strength in science and technology.</li> <li>Provision of individualized and optimal solutions to patients</li> <li>Access to healthcare</li> <li>Quality assurance and stable supply of products and services</li> </ul>	Challenges	Challenge to create innovative drugs and services, powered by new ideas and unique strength in science and technology	
<ul> <li>Safety of patients and clinical trial participants</li> <li>Co-creation of a healthcare ecosystem with society and community</li> <li>Human capital development</li> <li>Diversity, equity and inclusion</li> <li>Employee well-being</li> <li>Privacy protection and responsible use of digital technology</li> </ul>	Co-creation	Co-create new value that is truly needed, together with Roche and other diverse partners	
<ul> <li>Respect for human rights</li> <li>Corporate governance and stakeholder engagement</li> <li>Ethics, compliance and risk management</li> <li>Climate change and energy countermeasures</li> <li>Contribution to circularity and water management</li> <li>Protection of biodiversity</li> </ul>	Commitments	We lead in solving social issues with a focus on healthcare and act with integrity and forward thinking, toward realizing a sustainable society	

#### **Shared value**

# **Materiality Matrix**



### Mapping of impact assessment based on double materiality approach



Importance to business (Financial materiality)

- 1 Challenge to create innovative drugs and services, powered by new ideas and unique strength in science and technology
- 2 Provision of individualized and optimal solutions to patients
- 3 Access to healthcare
- 4 Quality assurance and stable supply of products and services
- 5 Safety of patients and clinical trial participants
- 6 Co-creation of a healthcare ecosystem with society and community
- Human capital development
- 8 Diversity, equity and inclusion

- 9 Employee well-being
- Privacy protection and responsible use of digital technology
- Respect for human rights
- Corporate governance and stakeholder engagement
- 13 Ethics, compliance and risk management
- Climate change and energy countermeasures
- (b) Contribution to circularity and water management
- 16 Protection of biodiversity

## **Definition of Material Issues**



### Establish Chugai's perspective and direction on material issues as a definition

Concisely express the issues Chugai should address as material issues

Specifically express the meaning of material issues, taking into account Chugai's intended direction

#	Material issue	Definition			
(ex	(example) ※All definitions of material issues are included in the Appendix				
2	Provision of individualized and optimal solutions to patients	We will generate evidence that enhances value for patients, continuously working to provide solutions that meet the diverse needs of individual patients and medical practices to strengthen and advance them.  Contribute to the provision of healthcare that is optimal for each patient and truly enhances value together with stakeholders involved in healthcare such as patients, their families, and healthcare professionals.			
6	Co-creation of a healthcare ecosystem with society and community	In order to support the foundation for sustainable patient-centric and advanced healthcare, and to expand healthy society, we collaborate with various entities such as society/community, patient group, government, administration, to create collective impact against social issues related to healthcare that cannot be solved by our company alone.  Through this, we will contribute to the maintenance, expansion and development of a robust foundation and ecosystem that supports medicine and healthcare as a leader in the industry.			

# Materiality, Strategy, and Performance Indicators



### Each division is committed to the related material issues for that division and its strategies

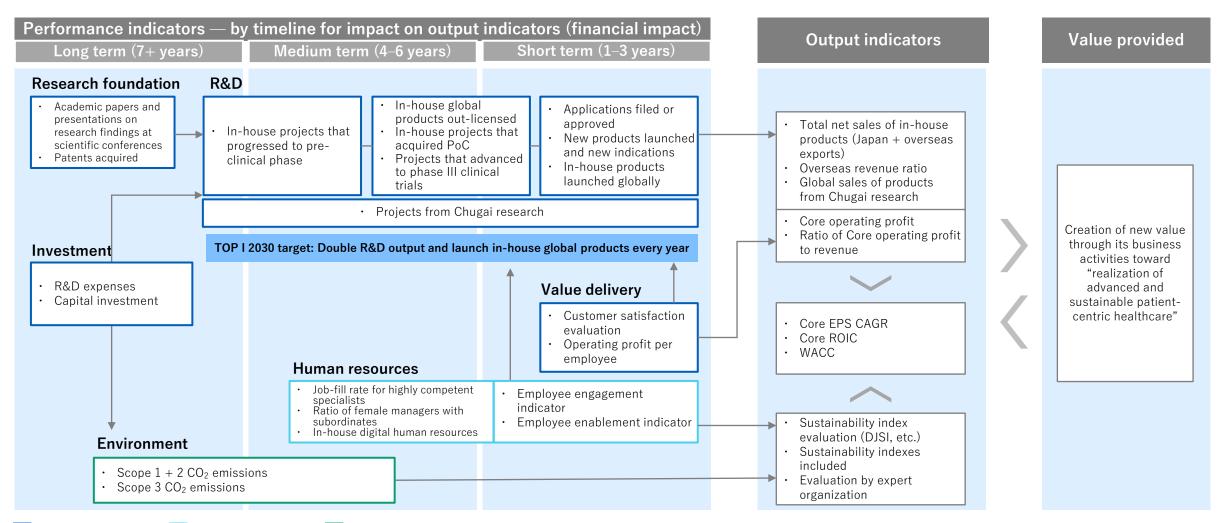
		Main positioning in management strategy*				
	Material issues		Enhancement of foundation for growth	Continuous promotion	Relevant performance indicators	
	Creation of innovative drugs and services, powered by unique strength in science and technology.	0			<ul> <li>In-house projects that progressed to pre-clinical phase</li> </ul>	
	Provision of individualized and optimal solutions to patients	0			<ul> <li>In-house projects that acquired PoC</li> <li>Projects that advanced to phase III clinical trials</li> <li>Applications filed or approved</li> </ul>	
Challenges	Access to healthcare	0			<ul> <li>New products launched and new indications</li> <li>In-house global products out-licensed</li> <li>In-house products launched globally</li> </ul>	
	Quality assurance and stable supply of products and services	0			<ul> <li>Academic papers and presentations on research findings at scientific conferences</li> <li>Patents acquired</li> </ul>	
	Safety of patients and clinical trial participants		0		<ul><li>Projects from Chugai Research</li><li>Operating profit per employee</li><li>Customer satisfaction evaluation</li></ul>	
	Co-creation of a healthcare ecosystem with society and community		0		<ul><li>R&amp;D expenses</li><li>Capital investment</li></ul>	
	Human capital development	0	0		Employee engagement indicator	
Co-creation	Diversity, equity and inclusion		0		Employee enablement indicator	
	Employee well-being		0	0	Job-fill rate for highly competent specialists	
	Privacy protection and responsible use of digital technology	0	0		Ratio of female managers with subordinates     In-house digital human resources	
	Respect for human rights			0	iii nodoc digital naman resources	
	Corporate governance and stakeholder engagement  Ethics, compliance and risk management		0	0		
Commitments	Climate change and energy countermeasures		0	0	Scope 1 + 2 CO <sub>2</sub> emissions	
	Contribution to circularity and water management		0	0	Scope 3 CO <sub>2</sub> emissions	
	Protection of biodiversity		0	0		

<sup>\*</sup> Growth strategy: (1)-(4) of the five areas of reform in TOP I 2030; Enhancement of foundation for growth: (5) of the five areas of reform in TOP I 2030 and medium- to long-term sustainability focus points; Continuous promotion: areas where initiatives for continuous reinforcement and advancement are already in place companywide and in each division

# Relationships of Value Creation Indicators



Organization of performance indicators based on the timeline for financial impact



# Definition of Material Issues (1/3)



Roche Ro	oche Group	

	# Material issue	<b>Definition</b>
1	Creation of innovative drugs and services, powered by unique strength in science and technology	To realize advanced and sustainable healthcare, continuously create innovative, high-quality drugs and services that address unmet medical needs. To achieve this, we will create original technologies mainly for drug discovery, and cultivate understanding of science and biology for disease.  Based on our value of patient-centricity, we aim to provide drugs and services that are centered on patients and reduce burdens on people around them such as caregivers and healthcare professionals and improve their QOL. To this end, we will actively adopt advanced technologies such as digital technology, and continuously work together with people around world on sophistication and acceleration of business processes for value creation, collaborate with academia, open innovation, advanced use of intellectual property, etc.
2	Provision of individualized and optimal solutions to patients	We will generate evidence that enhances value for patients, continuously working to provide solutions that meet the diverse needs of individual patients and medical practices to strengthen and advance them.  Contribute to the provision of healthcare that is optimal for each patient and truly enhances value together with stakeholders involved in healthcare such as patients, their families, and healthcare professionals.
3	Access to healthcare	We will contribute to regional healthcare coordination and enhancement of healthcare so that highly specialized medical care, mainly comprising innovative drugs and services that address unmet medical needs, can be delivered to people around the world who need it. We will realize continuous and sustainable creation of drugs and services by obtaining appropriate recognition for the provision of innovative drugs and services that have true value while taking measures such as cost reduction by proactive use of new technologies and promotion of treatment design with less burden for patients.
stable supply of products services, as well as information quality, throughout the product life cycle from the clinical trial stage. We will also make efforts and services counterfeiting and poor quality of drugs, such as enhancing traceability in the supply chain. In addition, in accordance with the		counterfeiting and poor quality of drugs, such as enhancing traceability in the supply chain. In addition, in accordance with the basic concept of quality, we will build a supply chain that is robust even in emergencies by working together with stakeholders in the value
5	Safety of patients and clinical trial participants	To ensure thorough management of safety throughout the product lifecycle and minimize potential negative impact such as deteriorating health to patients and clinical trial subjects. In addition to carrying out appropriate pharmacovigilance activities in cooperation with regulatory authorities, we ensure the provision of information to healthcare professionals to promote the proper use of drugs and services. Particularly in ensuring the safety of products and conducting clinical studies on development products, risks and efficacy shall be appropriately evaluated from the viewpoints of high ethics and science.

# **Definition of Material Issues (2/3)**



#	Material issue	Definition	
6	Co-creation of a healthcare ecosystem with society and community	In order to support the foundation for sustainable patient-centric and advanced healthcare, and to expand healthy society, we collaborate with various entities such as society/community, patient group, government, administration, to create collective impact against social issues related to healthcare that cannot be solved by our company alone.  Through this, we will contribute to the maintenance, expansion and development of a robust foundation and ecosystem that supports medicine and healthcare as a leader in the industry.	
7	Human capital development		
8	Diversity, equity, and inclusion	Foster an inclusive organizational culture that respects diverse thinking and ideas and challenges together to pursue innovation. In doing so, we will improve and correct imbalances that may be obstacles while creating opportunities for diverse human resources to play active roles. We will promote diversity, equity, and inclusion in all aspects of our business activities. Through these activities, we will contribute to the realization of an inclusive society that respects diversity.	
9	Employee well-being  We maintain a healthy, safe and secure work environment for employees. We believe that the health of employees is the foundation of a business activities, and we will actively promote activities that contribute to promoting the health of employees. In addition, we will improve the engagement of each and every employee, and promote the establishment of an environment where employees can work independently and autonomously, and have a sense of work satisfaction, motivation in life, and be active both physically and mentally.		
10	Privacy protection and responsible use of digital technology	Comply with regulations, collect and use data in a fair manner, build robust management mechanisms, and work with stakeholders to cope with appropriate personal information protection and information security. We will actively utilize digital and other new technologies with a high level of ethics while keeping in mind the changing environment and give an example to stakeholders and society.	

# **Definition of Material Issues (3/3)**



Roche	Roche	Group

#	Material issue	Definition	
11		We respect individual dignity and human rights as the right for every single person to live own life freely with peace of mind and pursue happiness. As a life sciences company, it is essential to not infringe on human rights. Based on this principle, we prevent, correct, and reduce violations of the human rights of employees involved in business activities and workers in the value chain, including their right to work.  We will continuously and effectively carry out this initiative, including information disclosure, throughout the industry.	
12	and stakeholder engagement	We appropriately manage important management items under a highly effective system that separates management decision-making from business execution and supervision. Ensure management autonomy and independence to achieve sustainable growth and increase corporate value.  Focusing on corporate accountability, we will strive for highly transparent and appropriate disclosure of information. At the same time, we will engage in dialogue with stakeholders to understand society's demands on our company, including courteous and easy-to-understand communication on pharmaceutical products and services.	
13	risk management	Ensure high ethical standards in all activities.  We will comply with laws and regulations, respond to the changing demands of society, and build open and cooperative relationships with stakeholders to ensure transparent and fair corporate activities. Establish basic principles of bioethics including biotechnology, promote understanding and compliance among employees, and strive to handle them properly while continuously showing our efforts as a role model to the industry.  In addition, we will centrally identify, organize, and visualize all risks related to our business activities. We will promote integrated, effective, and efficient risk management, and also promote activities based on the Risk Appetite Statement.	
14	energy countermeasures		
15		We actively strive to design and implement business activities that address the circular economy, including zero waste emissions, and contribute to the realization of a society in which resources are effectively used.  In view of social issues related to plastics, such as marine pollution, etc., plastic waste will be reduced and recycling will be promoted. In addition, we will work to optimize appropriate wastewater treatment and consumption throughout our value chain to promote water resource management, conservation, and recycling.	
16	Protection of biodiversity	Efforts for minimizing the impact on biodiversity shall be made including proper use and management of chemical substances, the prevention of air and soil pollution, and the reduction of the amount of hazardous chemical substances used and hazardous waste. Information disclosure for this efforts shall be openly conducted. We will work on natural regeneration in cooperation with various players to connect the irreplaceable Earth to the next generation.	





# Co-Creation of a Healthcare Ecosystem



Vice President In charge of External Affairs Dept.

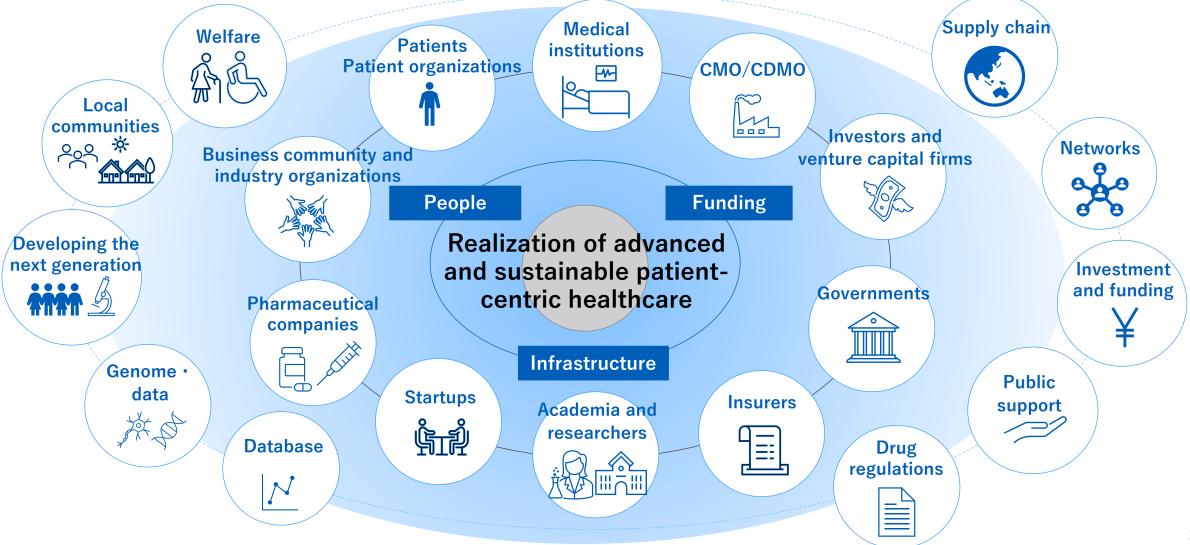
## Naoya Fujihara

### Co-creation of a Healthcare Ecosystem with Society and Community



We collaborate with various entities to resolve social issues in medicine and healthcare and realize advanced and sustainable patient-centric healthcare

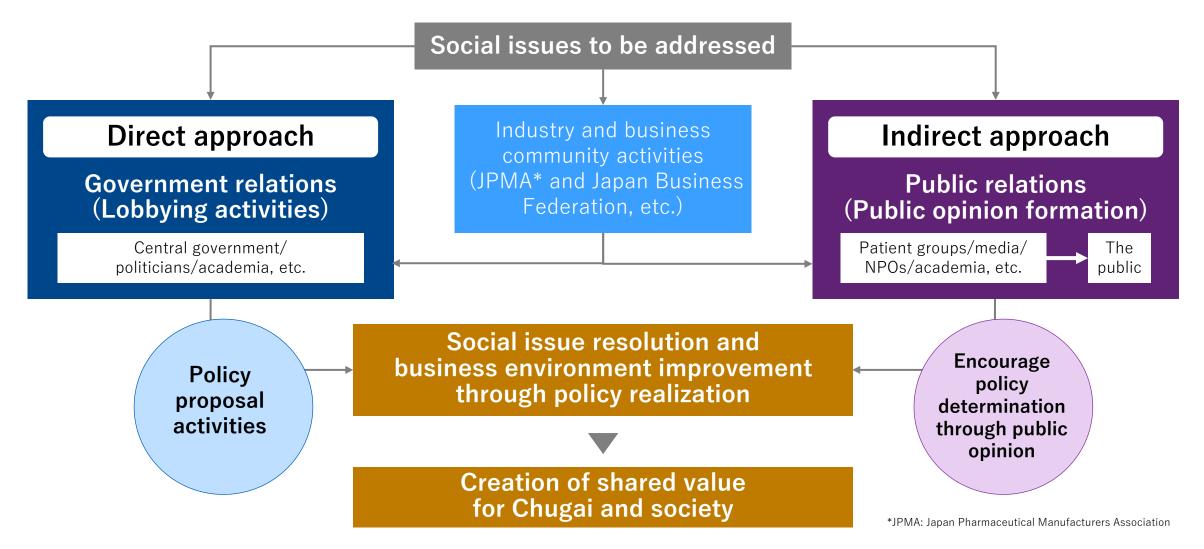




### **Toward Value Creation through Collaboration with Stakeholders**



We aim to create shared value for the Company and society using a unified direct and indirect approach



# The Company's Industry and Business Community Activities for Creation of Shared Value



Exercising leadership across industries to achieve social issue resolution and business environment improvement through policy realization

### **Industry activities**

Expressing opinions on resolution of issues and industry promotion in the pharmaceutical industry

The Federation of Pharmaceutical Manufacturers' Associations of JAPAN

Vice president (Chugai personnel: 14)

Japan Pharmaceutical Manufacturers Association

Vice president (Chugai personnel: approx. 120)

The Pharmaceutical Manufacturers' Association of Tokyo

President (Chugai personnel: 15\*)

Etc.

### **Business community activities**

Disseminating opinions with a strong impact across industries, such as the biotechnology

Japan Business Federation (Keidanren) Vice chair of the Board of Councillors

Chair of the Committee on Bioeconomy

Japan Bioindustry Association

President (Chugai personnel on assignment: 2) EU-Japan BRT\*\*
Principal

Etc.

#### Drivers

- Exertion of influence through the organic activities of multiple organizations for the promotion of policy proposals and advocacy activities that would present a high level of difficulty for the Company alone
- ✓ Demonstration of strong leadership through the increase of the Company's presence in each organization's activities

# Resolution of increasingly complex social issues through new value creation based on co-creation

<sup>\*</sup>Including two persons on assignment

<sup>\*\*</sup>BRT: Business Round Table. Chugai leads Working Party 2, which is responsible for Life Sciences & Biotechnology, Healthcare and Well-Being.

# Case Study 1: Biotechnological Transformation (BX)



Roche Roche Group

As a leader in biopharmaceuticals, we will contribute to the building of a bio-community in Japan through cooperation beyond the medical industry

#### Possibilities of biotechnology

- ✓ Genome sequencing and editing technology innovation and IT/AI technology popularization are expanding new manufacturing possibilities using bioresources
- Expanding their scope of application will enable both the resolution of social issues, such as environmental and resource problems, and sustainable growth industries
- ✓ Countries around the world, including the U.S. and China, are incorporating BX as a national strategy and international competition is intensifying



#### Red bio

Biopharmaceuticals/ vaccines/cellular and gene therapies, etc.



#### White bio

Functional materials/bioplastics, etc.



#### Green bio

High performance, high yield crops/ biomass fuels, etc.



Health and medical problems

Global environmental problems

Food and resource problems

Example of supporting the promotion of the bioindustry through business community activities (Japan Business Federation Committee on Bioeconomy)



Observation of bioventures and the domestic and international bioeconomy









Contribution to government strategy through multiple policy proposals\*



Policy proposal recommendations to the relevant minister (Photo: April 2024)

Photograph ©Keidanren

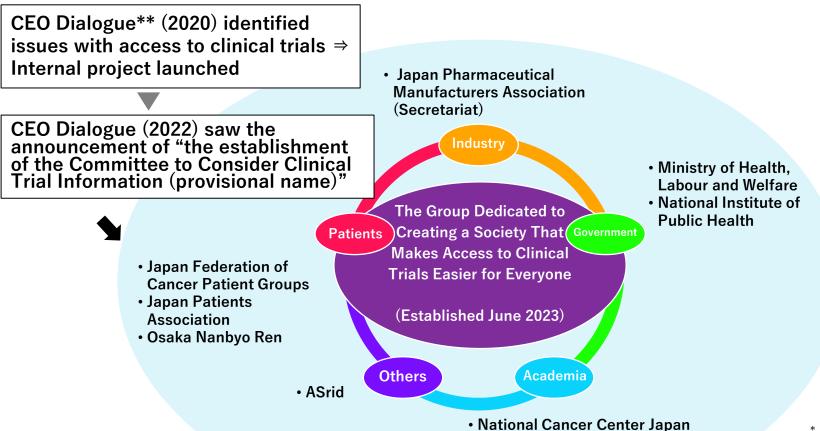
"BX Strategy—BX for a Sustainable Future (March 2023)," and "Key Initiatives for Achieving Biotechnological Transformation (BX) (April 2024)" are two proposals that we announced in tandem with the Cabinet's issuance of the "Bioeconomy Strategy (June 2024)"

### Case Study 2: The Group Dedicated to Creating a Society That Makes Access to Clinical Trials Easier for Everyone



Roche Roche Group

Picking up on front line issues related to clinical trial access in a joint effort among industry, academia, government, and patients to realize the reform of jRCT\*



#### **Results to Date**

- Four submissions of written recommendations for reform of jRCT
- Reflection in supplementary budget and budget request
- ✓ FY2024: ¥130 million (supplementary budget)
- ✓ FY2025: ¥470 million (budget request)

- Juntendo University Hospital
- National Institutes of Biomedical Innovation, Health and Nutrition

- ¡RCT: Japan Registry of Clinical Trials. Clinical trial submission and publication system (niph.go.jp)
- \*\* Dialogues with patient organizations and the CEO have been held every year since 2020

### Case Study 3: PHARMONY Activities for Incorporating Patient Feedback



Treating patients as partners in issue resolution and reflecting their feedback in every process from drug discovery research to post-market launch



PHARMONY is a coverall term for Chugai's activities for listening to the voices of patients and their families with the aim of mutual understanding, while engaging in initiatives for shared value creation.

Patients  $\times$  Pharma  $\times$  Harmony

Research

**Development** 

Approval and launch

Sales and postmarketing observation

- Cooperated with patient organizations to resolve all patient issues in all areas of the value chain ahead of other companies
- In research, obtained knowledge from the patient perspective through collaboration with patient organizations on three projects
- (1) Examination of drugs for chronic abnormalities in certain test values
- (2) Confirmation of patient perspective on importance of efficacy vs safety for disease A
- (3) Confirmation the impact of dosage form and dosage frequency in disease B





# Case Study 3: CHUGAI PHARMONY DAY 2024



### Communicating PHARMONY activities broadly inside and outside the Company

- ✓ Date: October 16, 2024
- ✓ Participants: Members of patient organizations, members of the media, Chugai Pharmaceutical Group employees
- ✓ Content: (1) Patient lecture, (2) Introduction of case studies of collaboration with patient organizations (five topics), (3) Dialogue between patient organizations and CEO



(1) Patient lecture



(2) Introduction by employees of case studies of collaboration with patient organizations



(3) Dialogue between patient organizations and CEO

### Case Study 3:

### [Reference] Collaboration with Patient Organizations Five Topics



Case studies of collaboration with patient organizations in all areas of the value chain were submitted

Topic	Issue	Expectation/Result
Research Initiatives for Examining Needs from a Patient Perspective in the Initial Stages of Drug Discovery Research	Differences between the views of patients and non-patients on "chronic abnormalities in blood levels of a certain substance X"	<ul> <li>Demonstrated the presence of latent patient needs</li> <li>Plan to formulate objective indicators in QoL evaluation points</li> </ul>
Formulation Listening to the Voices of Patients and Refocusing Our Thoughts on "Patient-Centric Drug Development" —Production Engineering Summer Camp Activities	<ul> <li>Creation of opportunities for dialogue between department personnel and patients</li> <li>Identification of latent needs in formulation</li> </ul>	<ul> <li>Increase motivation of all department personnel</li> <li>Creation of multiple ideas, such as easy-to-use formulation design</li> </ul>
<b>Development</b> Progress on Clinical Development by Advancing Together with Patients	Promoting understanding among patients of the significance of clinical trials and cooperation	<ul> <li>Creation of a Drug Discovery Collaboration Guide for patients</li> <li>Improvement of the thank you letter</li> </ul>
<b>Development</b> Reform of Compensation System Including Patients' Perspectives	Established an appropriate explanation of the delicate details of compensation	<ul> <li>Creation of compensation-related documentation that is easy for patients to understand</li> </ul>
Overseas Cooperation with Endometriosis Patient Support Organizations in the United States: Understanding the Unspoken Journey of Endometriosis	<ol> <li>Exploration of the following patient perspectives:</li> <li>Increasing recognition of endometriosis by physicians</li> <li>Establishment of non-invasive diagnostic methods for early diagnosis</li> <li>Treatment methods other than symptomatic treatment (pain medication) and surgery</li> </ol>	Plan to draft a white paper based on patient support organization opinions

# Towards the Realization of Advanced and Sustainable, Patient-Centric Healthcare



Simultaneous resolution of the three issues of innovation, cost, and access, to maintain and develop the healthcare ecosystem



- Building a drug discovery ecosystem open to the world
- Making the pharmaceutical industry a core industry supporting Japan's future growth by utilizing its scientific technological capability
- Increasing the efficiency of pharmaceutical development by establishing a healthcare information platform

### Creation of a healthcare ecosystem together with patients

- Change to a framework that enables patient participation in policy decisions and treatment
- Focus investment on items of high value to patients
- Cultivate social understanding of the importance of promoting innovation



### Cost

- Realizing sustainable public insurance
- Realizing a balance between public support, mutual assistance, and self-help



- Resolve drug lag/loss and problems with stable supply
- Ensure fairness in access to healthcare



# $\langle 04 \rangle$

# Our Challenge for PHC Solutions



Executive Vice President Supervisory responsibility for PHC Solution, Partnering and Special Mission for CVF

## Tetsuya Yamaguchi

# **Necessity of Personalized Healthcare (PHC) Solutions**



Increasing sophistication of patient needs makes maximizing the value provided by innovative drugs more important

Roche Roche Group

2030

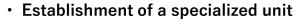
Focus and specialization on drugs Becoming a leading pharmaceutical company in Japan

- Becoming a Japanese leading **company** creating innovative drugs by focusing on the pharmaceutical business under the strategic alliance with Roche
- Promoting the spread of PHC as a **pioneer** in providing optimal treatment based on diagnosis of patients' genetic 2019 information, etc.

Challenge to find solutions that increase the value of pharmaceuticals

- Established the FMU\*, started the CGP\*\* business, significant contribution to cancer genomic medicine
- Started a drug-related solutions project as part of efforts for the insight business

#### **Establishing "PHC solutions"**



 Creation of PHC solutions that realize proof of value and maximization of value of drugs

 Achieving global development and approvals, building a supply structure, and securing business earnings

Clearly set out in the refinement of TOP 1 2030







Full-Scale Response to PHC Solutions Becoming a Necessity



# Definition of "PHC Solutions" and Value Created



Realize the material issue: "Provision of individualized and optimal solutions to patients"

**Definition of "PHC solutions"** 

Products and services such as SaMD\* and biomarkers that enable optimal therapy for individual patients by precisely diagnosing pathologies and measuring therapeutic effects

### Chugai's innovative drugs x PHC solutions = optimal therapy for individual patients

Enhanced demonstration of value in the R&D stage of drug discovery

**Value Created** 

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Maximization of clinical value of drugs

3

Creation of economic value as a solution business

\*SaMD: Software as a Medical Device

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# **Financial Impact of PHC Solutions**



### Accelerate R&D output and maximization of drug value

Examples of expected effects Value created Financial impact Evaluation of development project value New indicators for precisely measuring (drug price) Expansion of earnings from drug products treatment efficacy **Enhanced** Increase in development project demonstration of value in the R&D stage of Narrowing down patients through precise success rate cost drug discovery disease diagnosis Reduction in drug development Early market launch of **N** development projects VV Support for image diagnosis, measurements Maximization of outside medical facilities clinical value of drugs Streamlining of clinical development Objective quantitative indicators, 24-hour monitoring Increase in number of prescriptions and duration of use for launched products Creation of economic value as a solution Self-monitoring of treatment efficacy by business External provision as a solution service patients

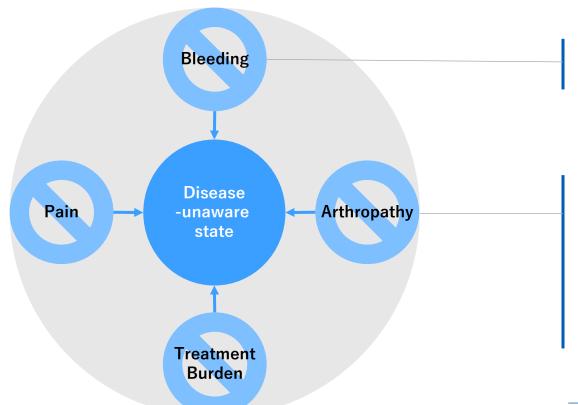
### Case Study 1: Joint Diagnosis Support Solution for the Hemophilia Field (1)



### A bottleneck for improving QOL for hemophilia patients

#### Vision and unmet needs in hemophilia treatment

#### Vision for hemophilia treatment\*



(+) Hemlibra realized prevention of bleeding with low frequency subcutaneous delivery (previous therapy centered on supplementation of blood clotting factors)

- (-) Joint bleeding (hemarthrosis) causes inflammation of joint linings (synovitis), progressing to the destruction of cartilage and bone, and restricting patient activity
- (-) Regular joint evaluation is important as arthropathy can present due to progression of bleeding, even when asymptomatic
- (-) MRI equipment cost and test time, and the high level of expertise required for ultrasound examination of joints have impeded their widespread use

→ Arthropathy is a key factor in reducing QOL

<sup>\*</sup>Created by the Company based on "Hermans C, Pierce GF. Towards achieving a haemophilia-free mind"

### Case Study 1: Joint Diagnosis Support Solution for the Hemophilia Field (2)



Developing a solution to assist in the interpretation of joint ultrasound images

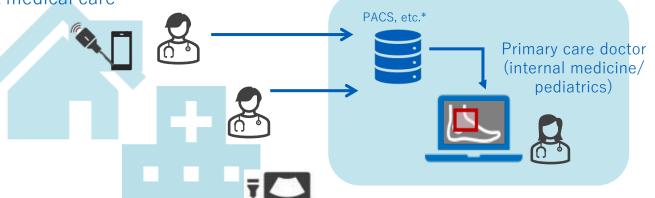


#### Image of solution in application

Image management system

Take ultrasound images of the joint during outpatient examination or home visit medical care

inside and outside hospital PACS, etc.\*

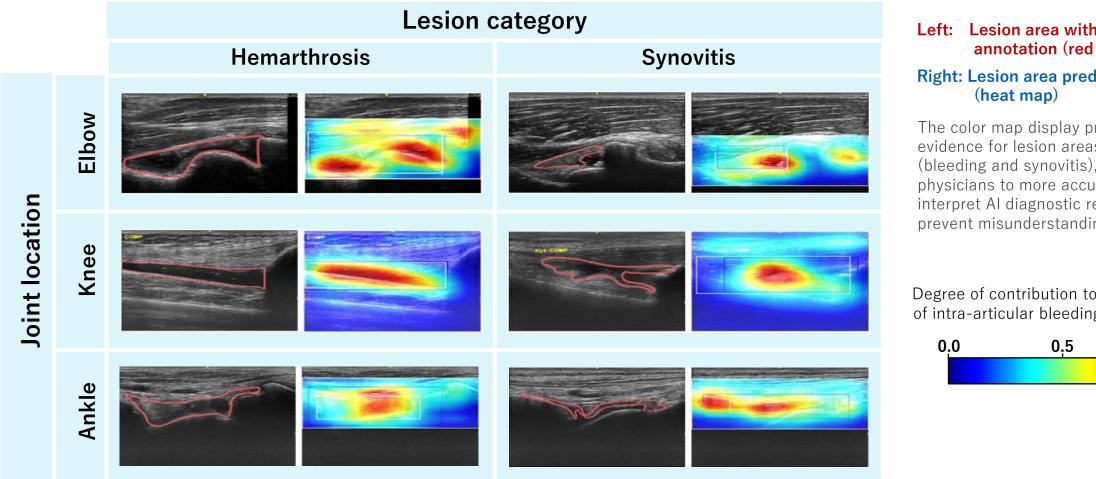


Utilizing AI to visualize lesion areas such as bleeding and synovitis, and to support the interpretation of joint ultrasound images requiring expertise. Aiming to reduce the barriers to joint assessment.

### Case Study 1: Joint Diagnosis Support Solution for the Hemophilia Field (3)



Example of a solution currently in development (visualization of joint lesions)



Left: Lesion area with physician's annotation (red frame)

Right: Lesion area predicted by Al

The color map display provides evidence for lesion areas (bleeding and synovitis), helping physicians to more accurately interpret Al diagnostic results and prevent misunderstandings.

Degree of contribution to the prediction of intra-articular bleeding and synovitis



Success in displaying lesion areas on joint ultrasound images by data acquisition and model building through clinical research

<sup>•</sup> Artificial intelligence-assisted ultrasound imaging in hemophilia: research, development, and evaluation of hemarthrosis and synovitis detection. Research and practice in thrombosis haemostasis. URL: https://www.rpthjournal.org/article/S2475-0379(24)00128-6/fulltext

<sup>· 46</sup>th Meeting of the Japanese Society on Thrombosis and Hemostasis (June 13, 2024)

<sup>· 65</sup>th ASH Annual Meeting and Exposition (December 10, 2023)

# Case Study 2: Solutions in Endometriosis



Examples of pain visualization and MRI image diagnostic support

In addition to therapeutic drugs, we are developing solutions to support appropriate evaluation, early diagnosis, and early treatment

#### **Current main treatments for endometriosis**

- Administration of hormonal agent to stop menstruation and ovulation
- Surgical removal



Currently developing endometriosis treatment (anti-IL-8 recycling antibody) with an approach different from hormone therapy, which is expected to improve the condition through its anti-inflammatory action.

### Towards resolving unmet needs in diagnosis and determination of treatment policy

#### Current diagnosis:

#### Subjective pain evaluation

- Individual differences in subjective evaluation
- Efficacy determination through clinical trials also shows variation

#### Laparoscopic lesion diagnosis

- Definitive diagnostic method. High diagnostic accuracy
- High patient invasiveness as diagnostic technique

#### Imaging device lesion diagnosis

- Minimally invasive evaluation method. Ultrasound and MRI as typical examples
- Diagnostic accuracy dependent on operator experience

#### Pain visualization solution

- Wearable device dBM\*
- Enables objective evaluation and 24-hour monitoring
- Precise pain evaluation enables more accurate understanding (monitoring)

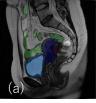


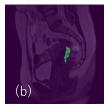
Embrace Plus by Empatica

#### MRI image diagnostic support solution

- Accelerate diagnosis by preventing oversight
- A diagnosis support algorithm that detects the following lesions in endometriosis
- (1) nodal lesions
- (2) adhesive lesions
- (3) endometriotic ovarian cyst
- Early therapeutic intervention
  - → Improved QOL by control of endometriosis symptoms
  - → Securing fertility by early start of infertility treatment

Example: detection model for nodal lesions





- (a) Segmentation results of lesions and peripheral organs
- (b) Display result showing uncertainty of predicted lesion
  Provided by Preferred Networks

\*dBM: Digital Biomarker

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# Roadmap to 2030



Establish a global supply system by 2030, and aim to launch multiple solutions in Japan and the United States

Phase 1	Phase 2	Phase 3	
2024 - 2025	2026 - 2027	2028 - 2030	2030
Cultivate a culture that generates "zero-to-one" innovation	Drive healthcare innovation in Japan	Drive healthcare innovation globally	Realization of PHC solution vision
Clinical app	lication of Chugai's PHC S	Solutions in global markets	Launch of new solutions in the U.S. (incl. partnership)
	Use in pharmaceutical R&D	<ul> <li>Market entry with Chugai's proprietary solutions</li> </ul>	
Promote commercialization	n by securing patient acces	ss in the Japanese market	Launch of new solutions in Japan (incl. partnership)
<ul> <li>Continuous expansion of the FMI I</li> <li>Use in pharm</li> </ul>	• Market entry with Rochermaceutical R&D	e's/Chugai's proprietary solutions	Introduce genomic medicine- related assays in Japan
Establish end-to-end solution	on promotion system and ca	pability	Fotoblish o global auguly
<ul> <li>Prepare development process and project promotion management structure</li> </ul>	<ul> <li>Strengthen technology exploration an affairs and regulatory compliance function</li> <li>Form collaboration with various stake</li> </ul>	ctions, etc.	Establish a global supply system

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### INNOVATION BEYOND IMAGINATION