

Innovation all for the patients



**CHUGAI PHARMACEUTICAL CO., LTD.**

A member of the Roche group

# **CHUGAI PHARMACEUTICAL CO., LTD.**

Sustainability Meeting

November 13, 2024

## Event Summary

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<b>[Company Name]</b>	CHUGAI PHARMACEUTICAL CO., LTD.	
<b>[Company ID]</b>	4519-QCODE	
<b>[Event Language]</b>	JPN	
<b>[Event Type]</b>	Analyst Meeting	
<b>[Event Name]</b>	Sustainability Meeting	
<b>[Fiscal Period]</b>		
<b>[Date]</b>	November 13, 2024	
<b>[Number of Pages]</b>	42	
<b>[Time]</b>	13:30 – 15:00 (Total: 90 minutes, Presentation: 63 minutes, Q&A: 27 minutes)	
<b>[Venue]</b>	Webcast	
<b>[Venue Size]</b>		
<b>[Participants]</b>		
<b>[Number of Speakers]</b>	7	
	Iwaaki Taniguchi	Director, Executive Vice President & CFO
	Yoshiyuki Yano	Executive Vice President, Supervisory Responsibility for Human Resource Management and ESG
	Tetsuya Yamaguchi	Executive Vice President, Supervisory Responsibility for PHC Solution, Partnering and Special Mission for CVF
	Norihisa Onozawa	Executive Vice President, Supervisory Responsibility for Corporate Planning, ASPIRE Transformation, Business Transformation and Digital Transformation Head of Corporate Planning Dept.
	Naoya Fujihara	Vice President, In Charge of External Affairs Dept.
	Kosuke Iijima	Head of PHC Solution Department

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	Kae Miyata	Head of Corporate Communications Dept.
<b>[Analyst Names]*</b>	Shinichiro Hyogo	Mitsubishi UFJ Trust and Banking Corporation
	Shinichiro Muraoka	Morgan Stanley MUFG Securities

\*Analysts that SCRIPTS Asia was able to identify from the audio who spoke during Q&A or whose questions were read by moderator/company representatives.

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# Presentation

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**Miyata:** Thank you very much for attending the Sustainability Meeting of CHUGAI PHARMACEUTICAL CO., LTD. today.

I'm Miyata from the Corporate Communications Department, and I will be your facilitator today. Thank you.

Today's event is held on an on-site basis and also distributed on a Zoom webinar basis at the same time. The agenda for today's meeting is shown on the venue screen, on the web screen and on the third page of the presentation materials. I will explain the contents accordingly.

Questions will be taken after all presentations have been completed. The Q&A session is expected to last 30 minutes, so we hope you will be proactive and ask questions. Please note that your audio will be muted during the presentation.

Now, Taniguchi will explain CHUGAI's value creation.

## Agenda



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

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**Taniguchi:** My name is Taniguchi, and I have been serving as CFO since April 1. I know that some of you will be seeing me for the first time, and it's my honor to work with all of you.

Thank you very much for joining us today. Over the next hour, I would like to give you a comprehensive introduction to our overall sustainability efforts.

As Miyata just mentioned, the meeting will be organized in this way: first, I will talk about the overall positioning of sustainability in our company and how it is linked to our value creation. Next, Yano, our executive vice president who is responsible for sustainability, will explain in more detail about the contents of our significant materiality review, which we had performed recently.

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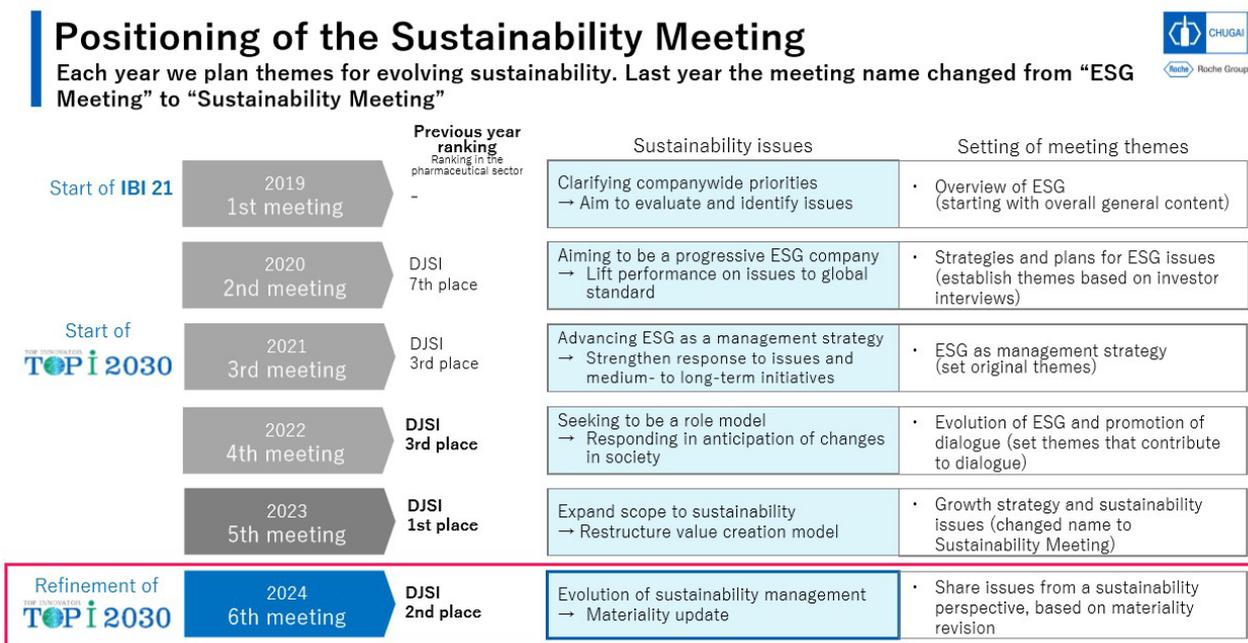
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After that, Fujihara and Yamaguchi will introduce two themes that are highly relevant to this year's materiality, and that we consider to be important social issues. They will introduce individual themes. We will proceed by such schedule today.

Now, let's start at the beginning. I would like to talk about the overall picture and structure of our value creation centered on sustainability at CHUGAI.



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This will be a topic related to the overall standpoint of a value structure centered on sustainability at CHUGAI.

First of all, we have held about 6 briefing sessions in the past. These sessions are actually positioned as briefing sessions; we have always held briefings with themes we set based on what we consider to be important sustainability issues at any given time. Since the last time, the name has been changed in such a way that the scope has been expanded to include sustainability, rather than ESG briefing.

This time, we have clearly stated this concept of sustainability in our basic management policy and strategy, and as I mentioned earlier, we have reviewed individual materiality on that basis. We intend to use this as a starting point to engage in dialogue with you and with various stakeholders on the issues and issues of focus.

We have changed the name of this sustainability briefing session since the last one, and I would like to talk again about the positioning of this session.

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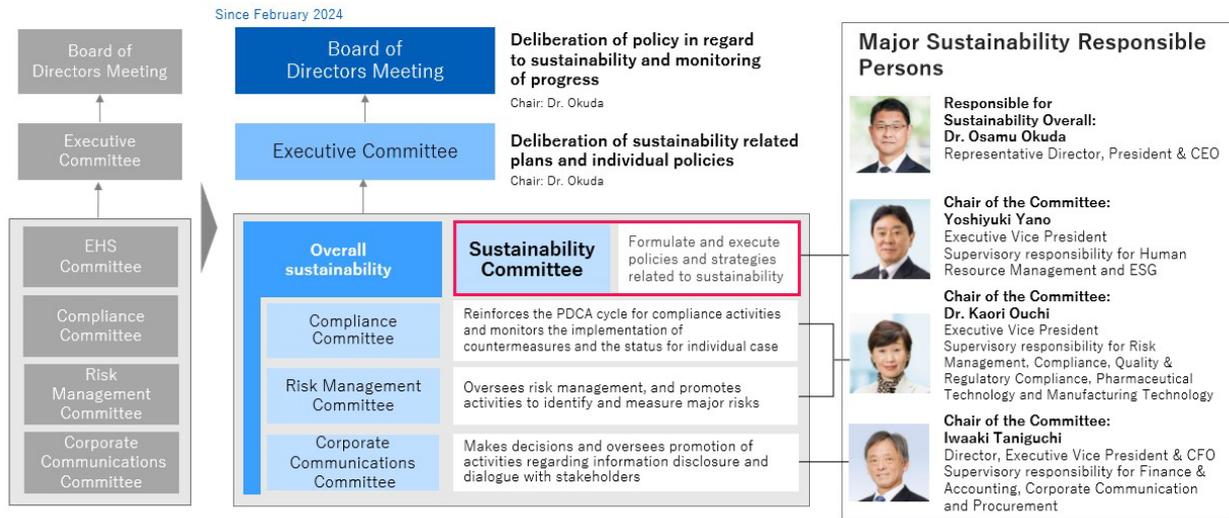
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# Sustainability Promotion System - Review of Corporate Management Committees -



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



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Last year we had a change in our management structure. As I mentioned earlier, in terms of the promotion system for sustainability, the EHS Committee, which had been in place until now, has been developed and dissolved into a newly named Sustainability Committee, chaired by Yano, who is with us here today, and we will promote comprehensive, in-depth, and wide-ranging discussions on this issue within the Company. I hope you will understand that we are now working on this promotion system by positioning this as a part of the Corporate Management Committees.

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# 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.

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Next page. As I mentioned earlier, we have reviewed our basic policy of our management this time. As we have written in blue here, we have made it considerably clear that we will manage our business with sustainability at the center of our business activities.

Our business activities are directly related to solving social issues. This is the very first step in sustainability, in other words. In this sense, I hope you will understand that we have clearly positioned sustainability at the center of our business activities.

The Sustainability Committee, which I mentioned earlier, is part of the Corporate Management Committees, and was the main focus of renewed discussions on the nature of sustainability and strategies for sustainability. We have naturally taken up the issue at the executive committees and the board of directors meetings and have deepened the discussion in various ways.

In this context, we have made a clear statement in this form and, moreover, have reviewed the materiality. In the second quarter of this year, at the financial results briefing in July, we introduced various aspects of our overall direction in the form of a refinement of our TOP I 2030 strategy, which is our strategy for the year 2030. As I have already mentioned, we are now in a situation where we can talk about the results of the review of materiality in detail after reviewing the individual specific material issues, and I would like to explain them in detail.

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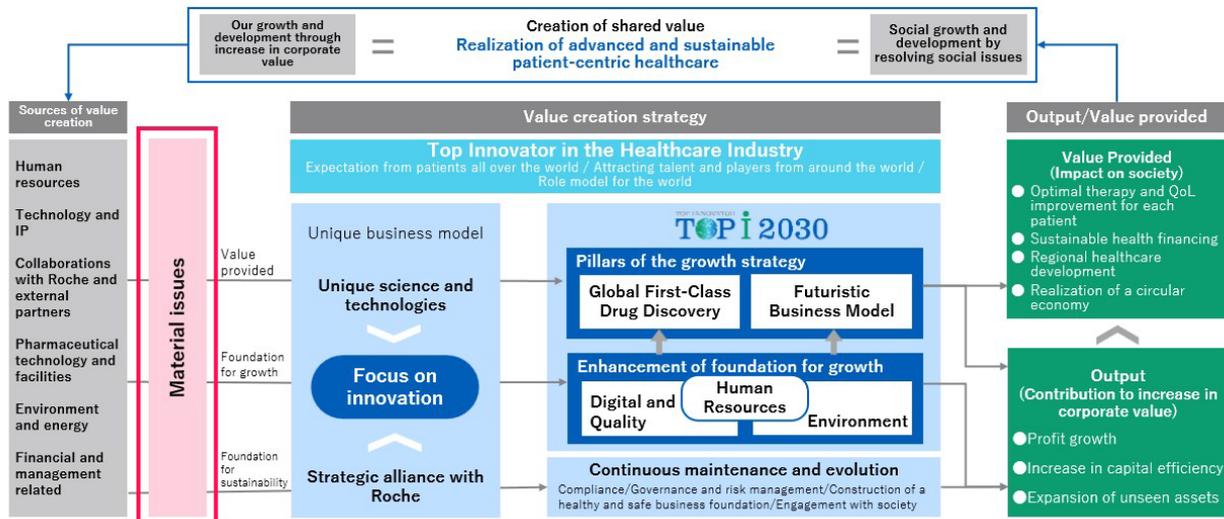
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# Previous Value Creation Model

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



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Before I get into the details of our detailed review of the material issues, I would like to take one look back at our value creation model. The value creation model has been around for several years now, and we recognize that it is a timeless and universal value creation model.

The starting point is the materiality on the far left, which is sublimated in our overall management strategy, and then transformed into concrete outputs and values on the far right. This is a series of stories, which is a model making very important basis of our management. As I have explained to you in the past, I believe that this is an important point of discussion and a starting point.

However, we have the impression that the linkage from materiality to output was a bit long and complicated, and difficult to understand in some aspects. This time, we have decided to take a further step into that area as well, and this model itself has been revamped, as we will introduce later.

The very materiality that I just mentioned, the most important starting point is this materiality on the leftmost side. We have reviewed this point this time. As we wrote here, the background is still the change in the external environment. After five or six years, in that context, we need to further improve the accuracy of our analysis and evaluation, and this will lead to an acceleration of activities in the field in terms of operation. We think these things will become more important.

The point is how to incorporate it into the business site. There are also some issues which became obvious after four to five years. The review of the material issues was conducted because it would be a good time to re-organize.

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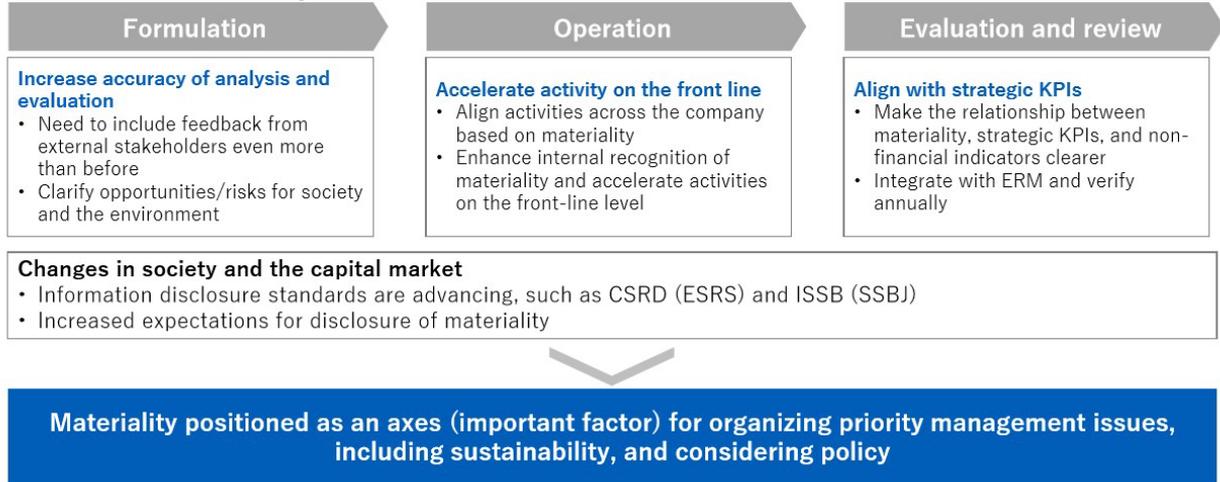


# Background for Materiality Review/Update

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



## Issues related to materiality



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The process of creating materiality, first of all.

The process is a PDCA-like process of formulation, operation, evaluation, and review, and this time, too, the process was carried out in a way that it was run internally. Yano will talk about the contents later, but for now, let's look at the next page, which is the value creation model I mentioned earlier. This is the newly organized content this time.

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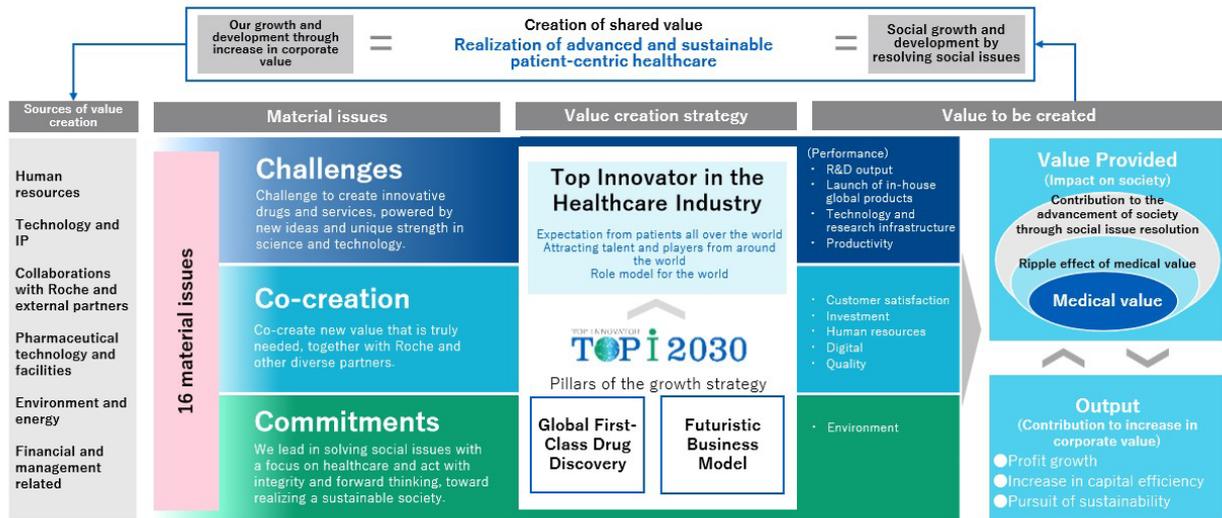
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# New Value Creation Model

A process for creating shared value using materiality as an axes



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The core, the structure has not changed significantly, but the starting point starts at material issues in the left, and the structure of how this leads to the value to be provided and created has not been changed. The material issues have been consolidated to 16, organized and consolidated in light of the changing times, and a model has been created that more directly and directly links the materiality to the value to be provided.

There are 16 material issues, which we have created this time, and we believe that they can be broadly grouped into three Cs. One is "Challenge". It's a discussion about what difficult issues we as CHUGAI need to face society and take on.

Next is "Co-creation". This is about co-creation with various partners, including our business partner Roche.

Then, "Commitments". I think this is commitments that we as a company are willing to make as a management strategy, and we guess that there are probably some parts that will be divided into these factors.

We believe that we will create value along these three axes and achieve output and value that will have an impact on society. We would appreciate it if you would take note of and remember this new value creation model.

However, as I mentioned in the Q2 financial results briefing, we will not change the axis of TOPI 2030, which is to become the top innovator in the healthcare industry after 2030, and we will continue to carry out this axis as the most important message of management.

In this context, materiality is positioned at the center of management strategy and business, and business strategy is promoted from this starting point. We clarify the position of materiality like this.

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# New Material Issues

Consolidate material issues into 16 items toward creation of shared value



\*Underlined sections indicate significant changes from the previous materiality

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



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

04 Initiatives introduced in 04  
03 Initiatives introduced in 03

02 Overview introduced in 02

Now, we have new 16 items of material issues this time, as I mentioned that we have consolidated them. Some of them overlap with the original concept, and some new ones have come in that don't. However, by consolidating the 16 items, the message will be easier to understand and convey, and actions can be taken in a more concrete manner. This is why we reviewed our materiality for the new 16 items.

The above is a comprehensive explanation of the review of material issues in the area of value creation. Yano will talk about the 16 items in more detail, and Fujihara and Yamaguchi will explain two more specific issues, and then we will proceed from there. This is how we would like to proceed with today's briefing.

This concludes my explanation. Thank you very much.

**Miyata:** Next, Yano will provide an overview of the materiality review.

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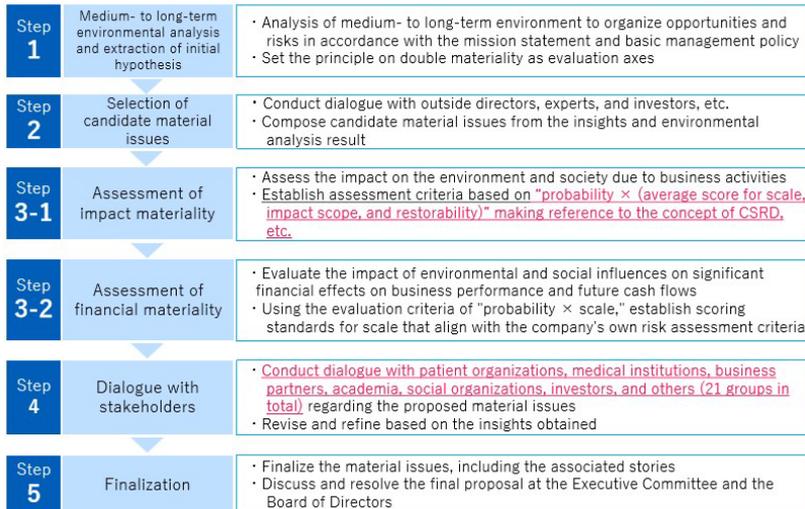


# Material Issues Reassessment Process

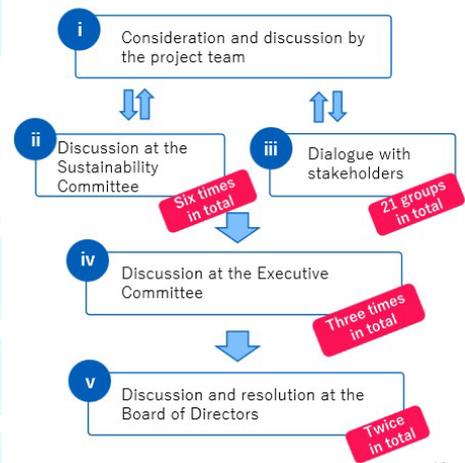


Emphasizing detailed analysis and stakeholder perspectives, based on double materiality approach

Process of identifying and finalizing material issues



Process of discussion and decision-making



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**Yano:** Hello, my name is Yano, and I have a supervisory responsibility for human resources management and ESG. As was mentioned earlier, I am also the chair of the Sustainability Committee.

I would like to introduce the overview of the material issues review.

First of all, our materiality was first created in 2019, and five years have passed since then. During that time, we have conducted annual inspections and reviews of our materiality, but the external demands and requirements for materiality have changed, and we ourselves have been promoting our TOP I 2030 growth strategy starting in 2021. In light of these changes in the environment, we have reorganized our key management issues, including sustainability.

In formulating the materiality again, we have considered five steps, as shown on the left. In particular, a major difference from the 2019 formulation is that we have refined the scoring of the materiality impact assessment in light of the progress made in the development of the sustainability disclosure standards.

We have also interviewed a wider range of external stakeholders, including healthcare professionals and patient groups, to gain insight into their expectations of CHUGAI and the social issues we should address.

As a result, from a long list of 60 candidates, as mentioned earlier, we finally narrowed it down to 16 items of material issues. As you can see in the chart on the right, based on the discussion by Sustainability Committee, the Management Committee and the Board of Directors have deliberated the issues thoroughly, and the Board of Directors in particular has discussed the unique story of the CHUGAI Group, and we finalized the issue.

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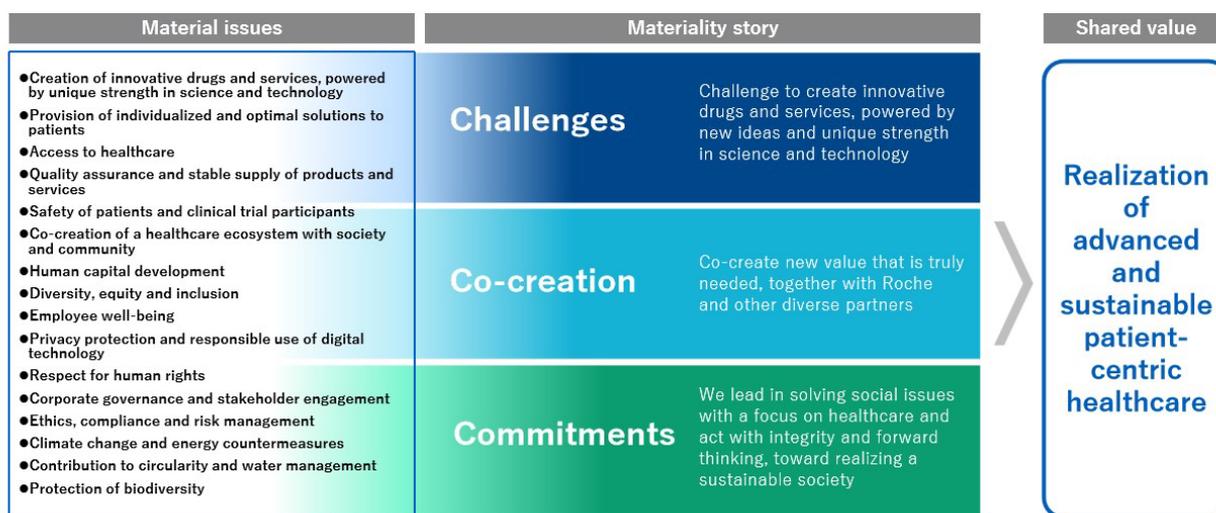
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# Materiality Story

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



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Following the formulation process described earlier, we have established 16 key issues as our materiality. We have organized the key issues we need to address into a story that can be easily shared with our employees and external stakeholders, based on three axes of Challenges, Co-creation, and Commitments.

Specifically, as Challenges, we at CHUGAI are committed to these 16 items of material issues, and by proactively addressing them, we will take on the challenge of creating innovative drugs and services, powered by new ideas and unique strength in science and technology .

Co-creation involves the co-creation of new values that is truly needed, together with Roche and other diverse partners.

And as Commitments, we lead in solving social issues with a focus on healthcare and act with integrity and forward thinking, toward realizing a sustainable society.

We will strive to realize advanced, sustainable, patient-centric healthcare that is a shared value between our company and society under these key factors.

The materialities on the left side of 16 items are linked to each other, and we would like to organize the story of three Cs, which are Challenges, Co-creation, and Commitments. By doing this, we will continue to develop this story through a variety of opportunities to gain the understanding and empathy of external stakeholders.

Let me explain Challenges, Co-creation and Commitments in more detail.

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# Materiality Story Based on Three Themes (1)

Challenge of creating innovative drugs and services



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The first Challenges is particularly important in solving social issues that we are working on, and is at the core of our business, which aims for shared value with society.

Specifically, we are committed to the following five items of material issues: creation of innovative drugs and services, powered by unique strength in science and technology, provision of individualized and optimal solutions to patients, access to healthcare, quality assurance and stable supply of products and services, and safety of patients and clinical trial participants. We are committed these five items of material issues to creating innovative drugs and services to address unmet medical needs for which there is still no cure or with low treatment satisfaction, powered by new ideas and unique strength in science and technology.

We believe that it is extremely important for us to address the key issues of this Challenges as part of our role in realizing this advanced and sustainable patient-centric healthcare, and we have reaffirmed this through dialogue with our stakeholders in the formulation of this materiality.

Challenges is a word that expresses CHUGAI's determination to continue to take on challenges based on what we have valued and cultivated in the past, such as advanced science, proprietary technologies, and a commitment to quality.

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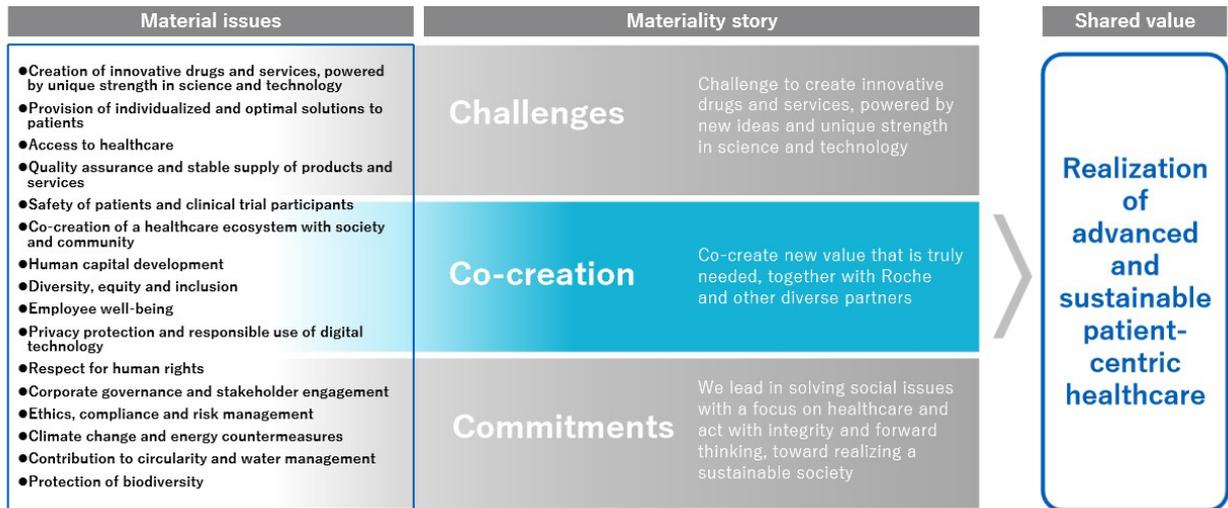
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# Materiality Story Based on Three Themes (2)

Co-creation of new value with diverse partners



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The next is Co-creation. We define this as the co-creation of new value that is truly needed, together with Roche and other diverse partners. As I mentioned earlier as the Challenges, the difficulty that we face today in medical issues and drug discovery is becoming increasingly difficult and are not easy to solve by our company alone.

Our goal is not just to create a cure, but to create new value for our customers and patients through the provision of such a cure. Co-creation of a medical ecosystem with society and communities, as stated in this materiality, we are considering joining hands with those who share our values and the direction we are aiming for and co-creating with them to solve social issues.

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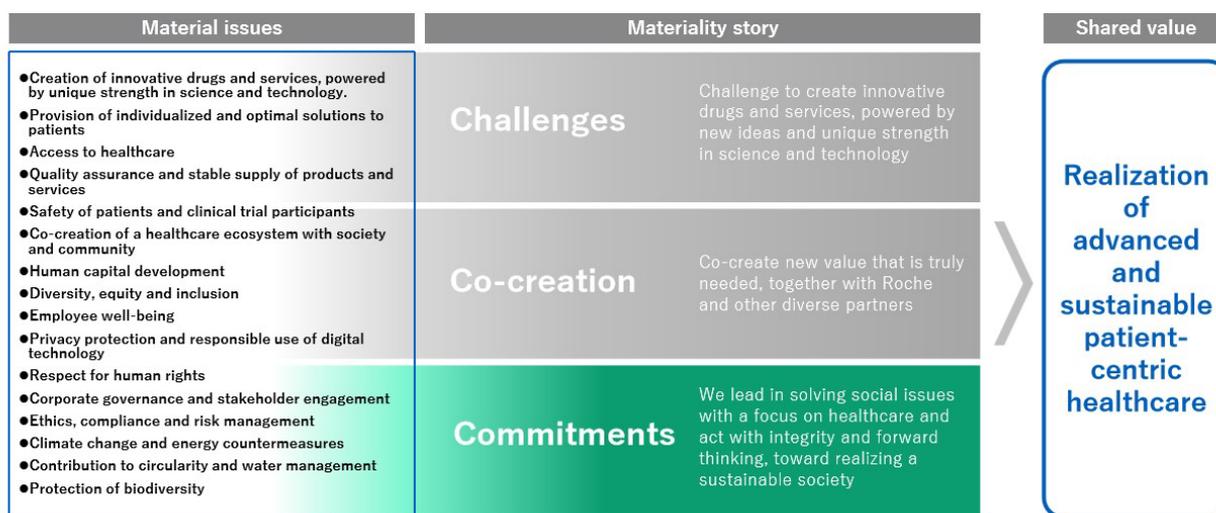
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# Materiality Story Based on Three Themes (3)

Commitments to working on solutions for social issues centered on healthcare



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The third axis is Commitments. It is our commitment to the realization of sustainable society. Sustainability is the global agenda, and it is a top priority for business as well.

Through our sustainability-centered business activities, we will actively address varieties of materiality, such as human rights, ethics, and global environmental measures, and act in a sincere and progressive manner to resolve social issues, with a focus on healthcare, toward a sustainable society.

We have reorganized the 16 items on the left side of the table this time. Through these 16 items of materiality and three Cs, we will strive to realize advanced and sustainable patient-centric healthcare.

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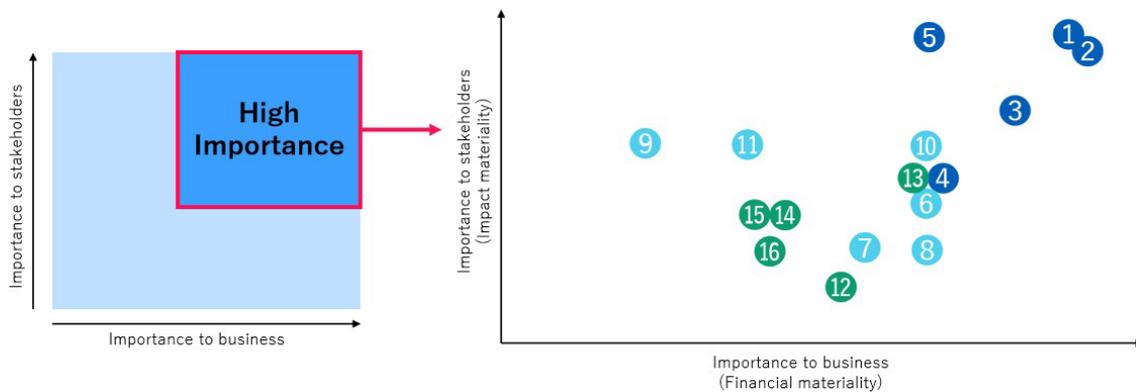
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# Materiality Matrix

Mapping of impact assessment based on double materiality approach



- |  |   |
|--|---|
| <ul style="list-style-type: none"> <li>① Challenge to create innovative drugs and services, powered by new ideas and unique strength in science and technology</li> <li>② Provision of individualized and optimal solutions to patients</li> <li>③ Access to healthcare</li> <li>④ Quality assurance and stable supply of products and services</li> <li>⑤ Safety of patients and clinical trial participants</li> <li>⑥ Co-creation of a healthcare ecosystem with society and community</li> <li>⑦ Human capital development</li> <li>⑧ Diversity, equity and inclusion</li> </ul> | <ul style="list-style-type: none"> <li>⑨ Employee well-being</li> <li>⑩ Privacy protection and responsible use of digital technology</li> <li>⑪ Respect for human rights</li> <li>⑫ Corporate governance and stakeholder engagement</li> <li>⑬ Ethics, compliance and risk management</li> <li>⑭ Climate change and energy countermeasures</li> <li>⑮ Contribution to circularity and water management</li> <li>⑯ Protection of biodiversity</li> </ul> |
|--|---|

※Classify by highly relevant story elements 18

The next slide introduces the materiality matrix.

Regarding the significance of materiality, we conduct impact assessments based on the principle of double materiality. We analyze opportunities and risks in terms of both the axis of a company's impact on society and the environment, and the impact of society and the environment on the Company and map them onto a matrix.

The important issues extracted by materiality are all of high importance, but as I explained earlier, there are five items of material issues identified as challenges, which in this case are number one through number five. These five items of material issues, shown in dark blue, are also important themes for our company, and are positioned as central to the creation of shared value between society and our company.

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# 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
(example) ※All definitions of material issues are included in the Appendix		
2	<b>Provision of individualized and optimal solutions to patients</b>	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	<b>Co-creation of a healthcare ecosystem with society and community</b>	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.

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On the next page is the definition of material issues. In the review of material issues this time, we have not only selected but also defined each material issue to clarify its significance to the Company.

As explained in the discussion process at the beginning of this meeting, the Sustainability Committee or the Board of Directors have been working on and polishing and discussing this definition, and it became an expression that reflects the Company's aspirations.

The definitions of all items of material issues are in this Appendix, but this slide shows a little bit about the definitions of the two items of material issues that will be presented in the part that follows.

The second is the material issue of the provision of individualized and optimal solutions to patients, and this is what we mean by this. We will continue to work on providing solutions that enhance value for patients and meet the diverse needs of their families and healthcare professionals and contribute to providing healthcare that is optimal for each individual and brings true value enhancement.

I hope to be able to talk about PHC solutions for patients and specific examples on these themes later in this briefing.

The sixth is the material issue of the co-creation of a healthcare ecosystem with society and the community. In this materiality, we are not only working within the traditional framework of social contribution, but also creating collective impact by collaborating with various entities such as patient groups, society, communities and government administrations. We would like to contribute to the maintenance and development of a sustainable, patient-centric healthcare infrastructure as a flag-bearer within the industry.

At this briefing session, we would like to introduce our efforts in medical ecosystem co-creation, which aims to solve issues in collaboration with various entities.

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# Materiality, Strategy, and Performance Indicators



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

	Material issues	Main positioning in management strategy*			Relevant performance indicators
		Growth strategy	Enhancement of foundation for growth	Continuous promotion	
<b>Challenges</b>	Creation of innovative drugs and services, powered by unique strength in science and technology.	○			<ul style="list-style-type: none"> <li>In-house projects that progressed to pre-clinical phase</li> <li>In-house projects that acquired PoC</li> <li>Projects that advanced to phase III clinical trials</li> <li>Applications filed or approved</li> <li>New products launched and new indications</li> <li>In-house global products out-licensed</li> <li>In-house products launched globally</li> <li>Academic papers and presentations on research findings at scientific conferences</li> <li>Patents acquired</li> <li>Projects from Chugai Research</li> <li>Operating profit per employee</li> <li>Customer satisfaction evaluation</li> <li>R&amp;D expenses</li> <li>Capital investment</li> </ul>
	Provision of individualized and optimal solutions to patients	○			
	Access to healthcare	○			
	Quality assurance and stable supply of products and services	○			
	Safety of patients and clinical trial participants		○		
	Co-creation of a healthcare ecosystem with society and community		○		
<b>Co-creation</b>	Human capital development	○	○		<ul style="list-style-type: none"> <li>Employee engagement indicator</li> <li>Employee enablement indicator</li> <li>Job-fill rate for highly competent specialists</li> <li>Ratio of female managers with subordinates</li> <li>In-house digital human resources</li> </ul>
	Diversity, equity and inclusion		○		
	Employee well-being		○	○	
	Privacy protection and responsible use of digital technology	○	○		
<b>Commitments</b>	Respect for human rights			○	<ul style="list-style-type: none"> <li>Scope 1 + 2 CO<sub>2</sub> emissions</li> <li>Scope 3 CO<sub>2</sub> emissions</li> </ul>
	Corporate governance and stakeholder engagement			○	
	Ethics, compliance and risk management		○	○	
	Climate change and energy countermeasures		○	○	
	Contribution to circularity and water management		○	○	
Protection of biodiversity		○	○		

\* 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

This slide shows a chart of how these items of material issues relate to management strategy. The growth strategies in the table are linked to the strategies for 4 of 5 areas of reform in TOP I 2030: Drug Discovery, Development, Pharmaceutical Technology, and Value Delivery.

In addition, the middle section, "Enhancement of foundation for growth" is also included in the "Foundation for Growth" of the fifth reform in TOP I 2030 and is also an area that we will focus on in our sustainability efforts, including human capital, risk management, and environmental measures.

The last one, continuous promotion, is an important issue in all business activities, and is divided into three axes, as an area where the entire company or department is constantly working to strengthen the Company.

On the far right, we have categorized the KPIs as relevant performance indicators, output indicators, and value provided as outcome in the value creation model. We have picked out the indicators that we place particular importance on and shown their relationship with materiality. We will continue to disclose the progress of this KPI in our annual reports.

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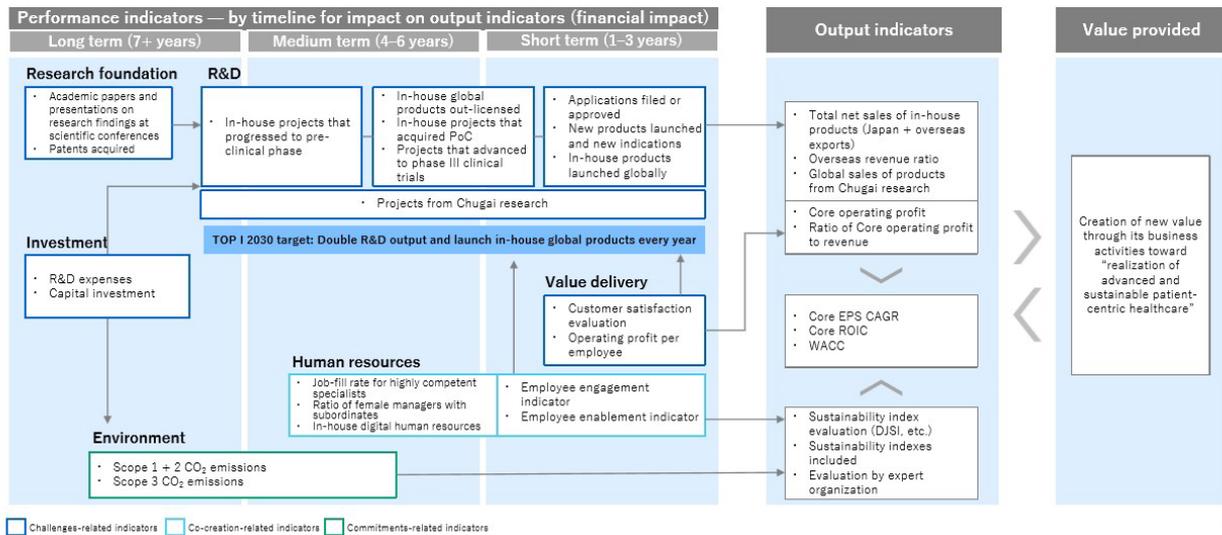
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# Relationships of Value Creation Indicators

Organization of performance indicators based on the timeline for financial impact



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This is the last slide. In this slide, we have organized the materiality and related performance indicators in relation to the output indicators and value provided as outcomes under the time frame in which the impact will appear.

The following indicators are listed from left to right: long term, medium term, and short term. They include long-term indicators such as research foundation, investment, and environment that require time to make an impact, R&D-related indicators such as the number of in-house projects that progressed to preclinical phase and the number of products approved for filing, which indicate performance in the short to medium to long term, human resource-related indicators such as the ratio of highly specialized human resources to the total number of employees, and value delivery indicators such as customer satisfaction. These are performance indicators and output indicators, which are similar to management targets, and show the relationship with output indicators such as sales and operating profit.

The performance of each R&D indicator constitutes the TOP I 2030 goals of "Double R&D output" and "Launch global in-house products every year". In order to achieve this goal, the continuous creation of innovation that can only be produced by CHUGAI is a very important key, and the source of such innovation is human capital, or human resources, which I believe is indispensable.

From this perspective, we have prepared a "People & Culture Report," which I believe is distributed on your desks, summarizing our unique human resource initiatives, indicators, and progress. I hope you will find it useful.

I would like to end my part with this. Thank you.

**Miyata:** Next, Fujihara will explain about co-creation of medical ecosystem. There will be a short pause at the beginning, so if you would like to take a screen capture, please use this opportunity. Now, let us begin the presentation.

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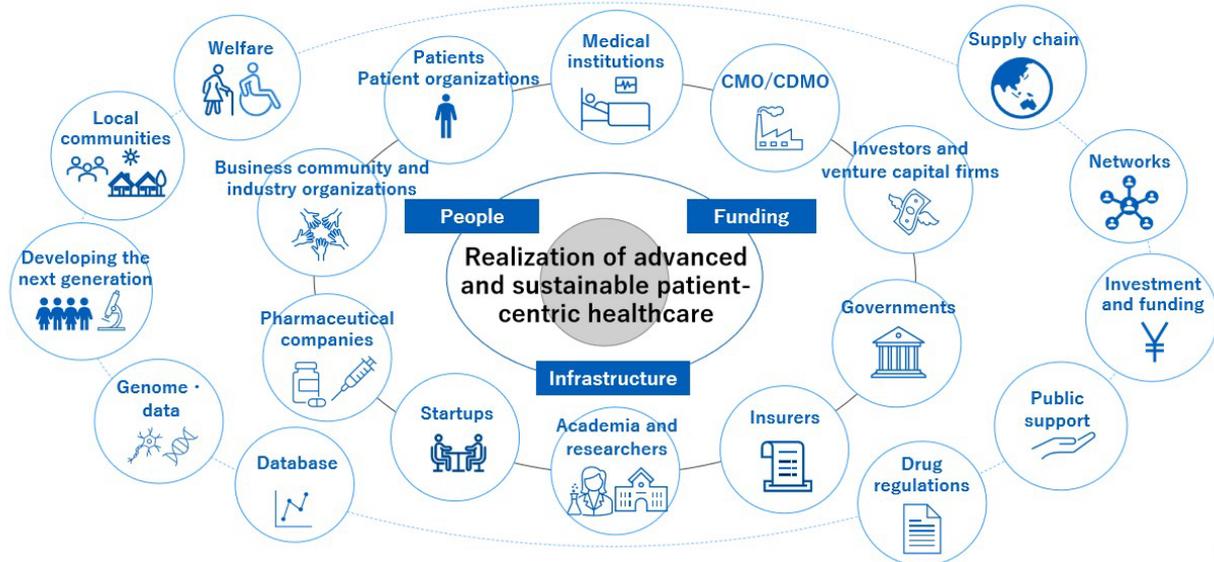
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## Co-creation of a Healthcare Ecosystem with Society and Community



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



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**Fujihara:** My name is Fujihara, and I am in charge of external affairs. I would like to explain one specific theme of the material issues: the co-creation of a healthcare ecosystem.

First of all, I would like to mention what Chugai's goal is in this healthcare ecosystem. As mentioned in Taniguchi's presentation at the beginning of this meeting, our basic management policy is to realize advanced and sustainable patient-centered healthcare.

Our main business, the creation of innovative drugs and services, is directly related to the realization of this goal, but we also want to create a collective impact by involving various stakeholders, as you can see, in solving social issues regarding healthcare.

In particular, we want to somehow solve the problems that patients have, who are the ultimate consumers of pharmaceutical products. We strongly feel this way. Chugai aims to be a top innovator. We intend to lead the industry in efforts to maintain and develop such a healthcare ecosystem.

Today, I would like to explain the function of external affairs, of which I am in charge, with a focus on policy-oriented activities.

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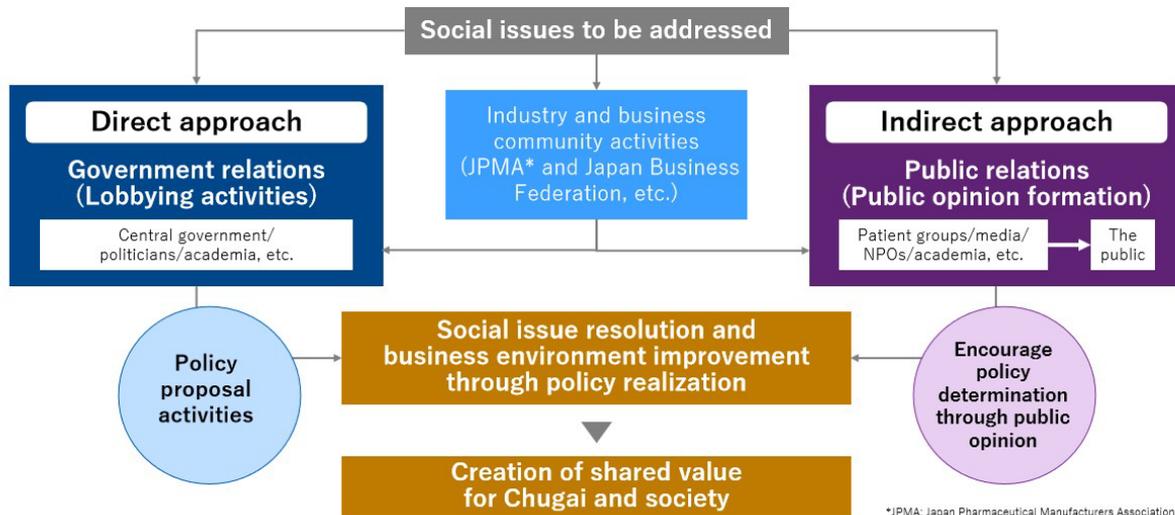
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## Toward Value Creation through Collaboration with Stakeholders

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



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This slide shows the framework for working with stakeholders. We are taking two approaches to address the issue. The left-hand side of the page shows the direct approach, which includes policy advocacy, lobbying, and direct outreach to policy makers.

On the other hand, the right-hand side of the diagram shows indirect approaches, which are activities that support policy decisions through public opinion, such as building public opinion and fostering understanding of policy development.

By using both of these, we hope to realize our policies, solve social issues, and strengthen our company's growth foundation.

While Chugai individually are actively engaged in such activities, the number of social issues that are difficult for individual companies to solve on their own is increasing, and the importance of the industry and business community activities described in the center of the slide is growing.

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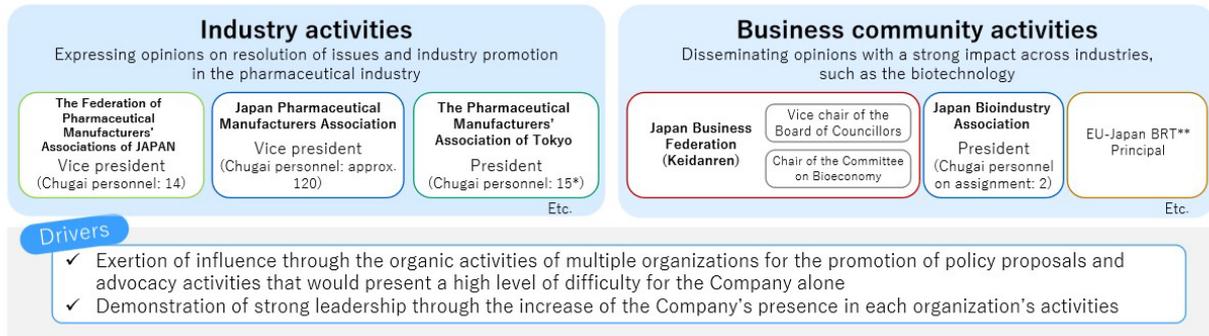
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# The Company's Industry and Business Community Activities for Creation of Shared Value



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



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

\*Including two persons on assignment  
\*\*BRT: Business Round Table. Chugai leads Working Party 2, which is responsible for Life Sciences & Biotechnology, Healthcare and Well-Being.

One of the characteristics of our industry and business community activities is that we play an active role not only in the pharmaceutical industry, but also in the business community activities, such as the Keidanren (Japan Business Federation). We believe that strengthening the presence of the pharmaceutical industry in the economy will be essential for the industry to exert a stronger influence.

On the left side, you will see industry activities, which are mainly the activities at the Pharmaceutical Manufacturers Association of Japan (PMAJ), an association of R&D-oriented pharmaceutical companies. Currently, our president & CEO, Dr. Okuda, is serving as vice president, and 120 people among all employees are involved in the activities of the PMAJ, which we believe is one of the highest levels in the industry.

On the other hand, we also have business community activity shown on the right. As the Company the vice chairman of Keidanren belongs to, we are working to create an environment in which the business community can generate innovation beyond the boundaries of industry, while taking advantage of the strengths we have built up to date, such as in the field of biotechnology.

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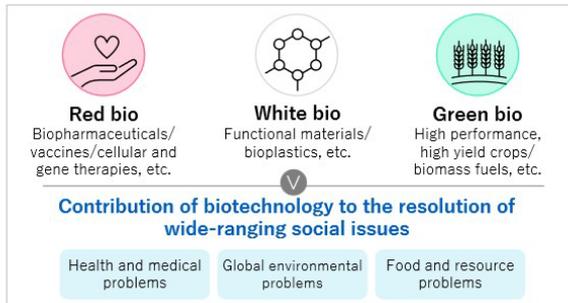
# Case Study 1: Biotechnological Transformation (BX)



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**



## 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

Collaboration with over 100 committee companies and discussion with government agencies, legislators, and experts in Japan and overseas

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)"

Now, I would like to introduce three examples of co-creation with external stakeholders.

The first is biotransformation activities. First of all, as shown on the left, we believe that biotechnology has the potential to help solve a wide range of social issues, not only in health and medicine, but also in the global environment, food, and resources, as well as contribute to the growth of the Japanese economy by creating new industries.

On the other hand, Japan was far behind other countries, and this was a problem shared by the public and private sectors. For example, in the U.S., the Biden administration has issued a presidential decree on a biotechnology strategy for 2022, which predicts that the future biotechnology market will be worth JPY4,000 trillion, and is making intensive, strategic investments.

In this context, we are participating in Keidanren's Bioeconomy Committee as the chair company. Currently, more than 100 member companies participate in this committee, and the industrial world is paying a great deal of attention to this committee. Working with the companies participating in the committee, we have exchanged opinions with bio-ventures, the domestic and international biotech community, experts, and government officials, and have compiled and published two policy proposals as Keidanren.

In June of this year, the Cabinet Office of the Japanese government released the Bioeconomy Strategy, which reflects the recommendations of the Keidanren, and we believe that it is a more effective government strategy.

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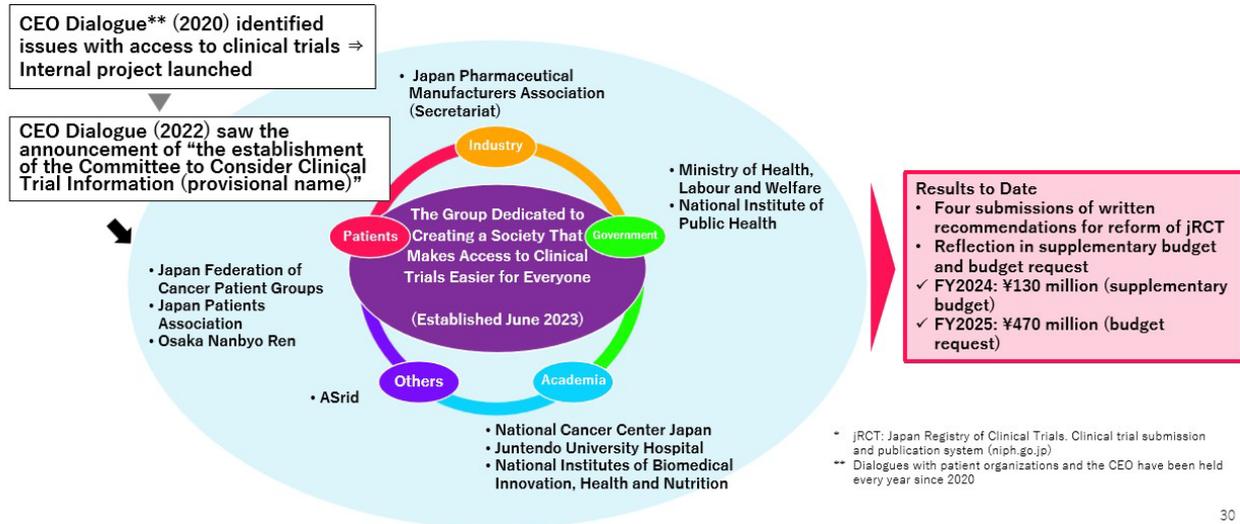
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## Case Study 2: The Group Dedicated to Creating a Society That Makes Access to Clinical Trials Easier for Everyone

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\*



And the second one. It is an activity of the Group Dedicated to Creating a Society That Makes Access to Clinical Trials Easier for Everyone. The impetus for this activity came from a dialogue between our CEO and a patient group in which a patient raised the issue of clinical trial information.

Specifically, the basic premise is that information about clinical trials is currently provided to patients through their health care providers. Then, patients receive existing treatment without knowing about the clinical trials. It was that there are many cases where patients are missing the opportunity to participate in clinical trials.

In response to this, we started a project within the company to share this sense of challenge with various stakeholders, so we reached out to various stakeholders and held a workshop. The workshop participants founded the Group Dedicated to Creating a Society That Makes Access to Clinical Trials Easier for Everyone in June 2023. The Ministry of Health, Labor and Welfare is also participating in this group.

The group has been quite energetic in its activities and has submitted requests for the improvement of jRCT, a database and information system for clinical research, on four separate occasions. As a result, these requests were reflected in the supplementary budget for fiscal year 2024 and in the budget request for fiscal year 2025. We believe that this is an example of how the voices of patients have led to the realization of policies through collaboration with various stakeholders.

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## 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 × Pharma × Harmony



- 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



Exchange of opinions in small groups



Holding workshops

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The third is the activity of PHARMONY. PHARMONY is a coined word that combines the words patients, pharma, and harmony, and is an internal initiative to incorporate the voices of patients and their families throughout the entire value chain, from the drug discovery research to the post-marketing stage.

In particular, Chugai is unique in that it focuses on collaboration in the drug discovery research stage. Three research projects are already working on drug discovery that incorporate patient feedback. For the researchers, it is not only a way to gain new knowledge, but also to enhance their sense of mission and motivation.

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# 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

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In October of this year, we held a CHUGAI PHARMONY DAY to share these PHARMONY initiatives both within and outside the Company.

In addition to the patient's lecture, our employees introduced examples of our collaboration with patient groups, and then President Okuda had dialogues with participants. We are hoping that by having the journalists involved and spreading the word outside the company through their publication, these kinds of activities will spread throughout the industry.

## 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
<b>Research</b> Initiatives for Examining Needs from a Patient Perspective in the Initial Stages of Drug Discovery Research	<ul style="list-style-type: none"> <li>• Differences between the views of patients and non-patients on "chronic abnormalities in blood levels of a certain substance X"</li> </ul>	<ul style="list-style-type: none"> <li>• Demonstrated the presence of latent patient needs</li> <li>• Plan to formulate objective indicators in QoL evaluation points</li> </ul>
<b>Formulation</b> Listening to the Voices of Patients and Refocusing Our Thoughts on "Patient-Centric Drug Development" —Production Engineering Summer Camp Activities	<ul style="list-style-type: none"> <li>• Creation of opportunities for dialogue between department personnel and patients</li> <li>• Identification of latent needs in formulation</li> </ul>	<ul style="list-style-type: none"> <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	<ul style="list-style-type: none"> <li>• Promoting understanding among patients of the significance of clinical trials and cooperation</li> </ul>	<ul style="list-style-type: none"> <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	<ul style="list-style-type: none"> <li>• Established an appropriate explanation of the delicate details of compensation</li> </ul>	<ul style="list-style-type: none"> <li>• Creation of compensation-related documentation that is easy for patients to understand</li> </ul>
<b>Overseas</b> Cooperation with Endometriosis Patient Support Organizations in the United States: Understanding the Unspoken Journey of Endometriosis	Exploration of the following patient perspectives: <ol style="list-style-type: none"> <li>1) Increasing recognition of endometriosis by physicians</li> <li>2) Establishment of non-invasive diagnostic methods for early diagnosis</li> <li>3) Treatment methods other than symptomatic treatment (pain medication) and surgery</li> </ol>	<ul style="list-style-type: none"> <li>• Plan to draft a white paper based on patient support organization opinions</li> </ul>

23 topics were submitted for CHUGAI PHARMONY DAY 2024

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For your information, these are the titles of the five presentations in collaboration with patient groups.

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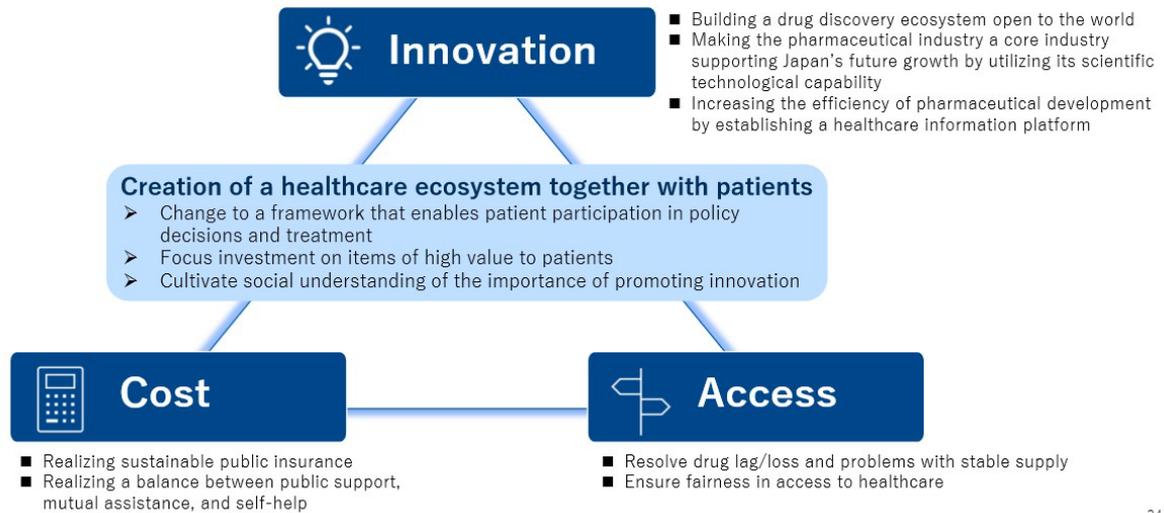
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# Towards the Realization of Advanced and Sustainable, Patient-Centric Healthcare



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



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This is the last slide.

Chugai's goal is to realize advanced and sustainable, patient-centered healthcare. In other words, we see this as our Challenge to simultaneously address the issues of patient access, advanced innovation, and cost.

These are the relationships of a trilemma: if, for example, the government's costs would be inflated if everyone has access to innovation, on the other hand, if the government's costs are borne by the patient, the patient's access will in turn be restricted. Then, why not lower the price of innovation? However, this will prevent reinvestment in research and development, and this will prevent innovation from being born in Japan in the future. That is the problem we are facing.

We believe that co-creation working with patients is one way to solve this trilemma. Specifically, patients are encouraged to participate in their medical care and to choose the best treatment for themselves. This will eliminate waste. The second point is to invest heavily in treatments and services that are of high value to the patient, thereby ensuring a more balanced allocation of resources. We also believe that it is important to foster public understanding of innovation and to improve health literacy so that people can understand it correctly.

Regarding the bioeconomy that was introduced at the beginning, the policy recommendation suggests that the business community should work to foster this public understanding beyond the boundaries of industry.

Access to clinical trial information that was introduced second, was an example that patients participated to policy making, and is also an initiative to expand the range of treatment options in the form of clinical trials.

In the last case, PHARMONY, we are working to create drugs with high value for patients by incorporating the voices of patients into drug discovery research.

Finally, Chugai positions patients as partners in value creation. We will continue to focus on creating a place where diverse stakeholders, including industry, academia, and government, as well as patients, can share their wisdom as equal partners and find optimal solutions.

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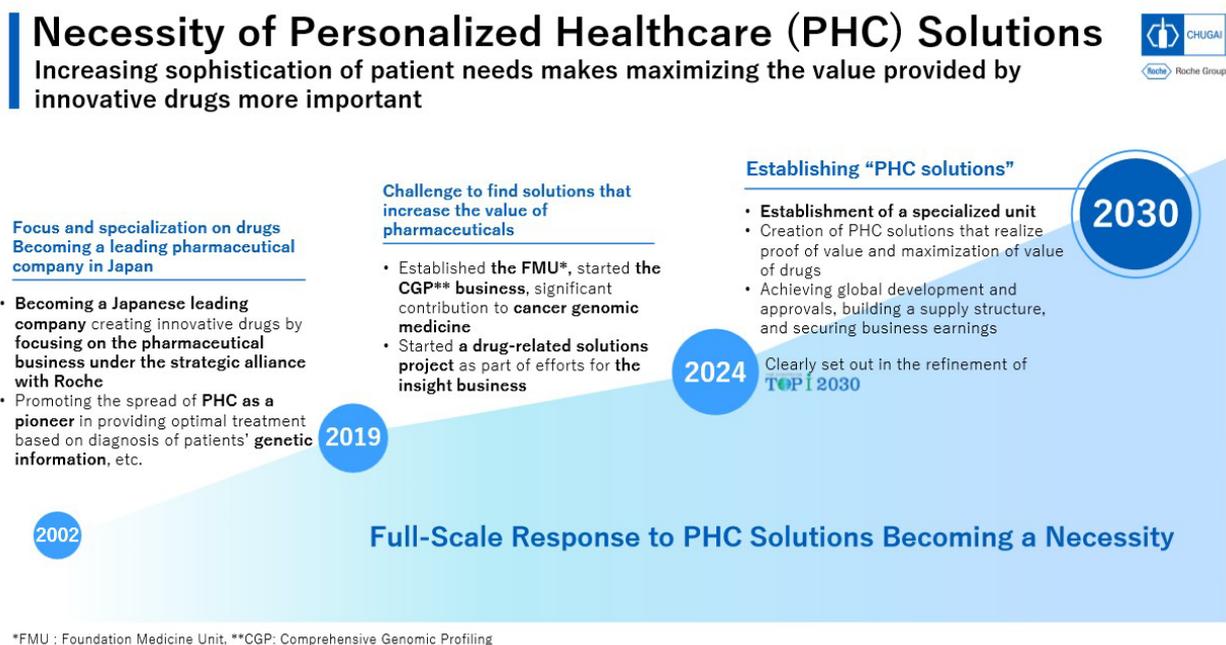
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This is all from me.

**Miyata:** Finally, Yamaguchi will explain the challenge for PHC solutions. There will be a short pause at the beginning, so if you would like to take a screen capture, please use this opportunity. Now, let us begin the presentation.



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**Yamaguchi:** My name is Yamaguchi, and I am in charge of PHC Solutions, Partnering and Special Mission for CVS. Thank you.

In April of this year, CHUGAI PHARMACEUTICAL launched a new organization, the PHC Solutions Unit, with approximately 70 employees. Digital progress has given birth to many solutions in the world.

PHC solutions, as described by CHUGAI, will be digital medical devices and services that precisely measure pathological conditions and treatment effects. This approach is consistent with a Material issue of providing individualized and optimal solutions to patients.

I, as the head of the unit, would like to explain the background and goals of its establishment. First of all, let me explain the background of CHUGAI's strategic alliance with Roche in 2002. By divesting its general pharmaceuticals and diagnostics businesses and specializing in pharmaceuticals for the medical market, CHUGAI has focused on creating and providing innovative drugs and has achieved significant growth.

In the field of oncology, we have launched molecular targeted drugs such as Herceptin and Alecensa and are leading the way as a pioneer in personalized cancer treatment. In addition, as of 2019, we obtained approval and launched F1CDx, a comprehensive cancer genome diagnostic, as a programmed medical device. This year marks the fifth anniversary of the launch of the product, which has grown to JPY7.7 billion in sales and is expected to measure 19,000 samples, promoting cancer genome medicine.

In addition, under our TOP I 2030 growth strategy, we have taken on the challenge of developing an insight business that extracts insights from large-scale data, and we have initiated a number of in-house solution projects related to our own pharmaceutical products.

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On the other hand, it has become clear that working on this PHC solution will require a different expertise and business model than the pharmaceutical business. Therefore, in April of this year, we established a unit specializing in PHC solutions, and by consolidating the activities that had been dispersed throughout the company into a single unit, we intend to engage in the PHC solutions business in earnest in the future.

## 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



\*SaMD: Software as a Medical Device

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Once again, CHUGAI defines PHC solutions as products and services such as SaMD and biomarkers that deliver optimal treatment to individual patients by precisely measuring pathological conditions and treatment effects.

CHUGAI's reason for working on solutions is that we believe that by combining CHUGAI's innovative pharmaceuticals with PHC solutions, we can achieve optimal treatment for each individual patient. There are three sources of value creation. One is that the proof of value in the development of drugs is becoming more advanced. Second, the clinical use of pharmaceuticals maximizes therapeutic efficacy. And the third will be the revenue from the solution itself.

In general, the solution business is very difficult to monetize. We are particularly trying to expand the value of the pharmaceutical business, as indicated in one and two, in order to achieve a return.

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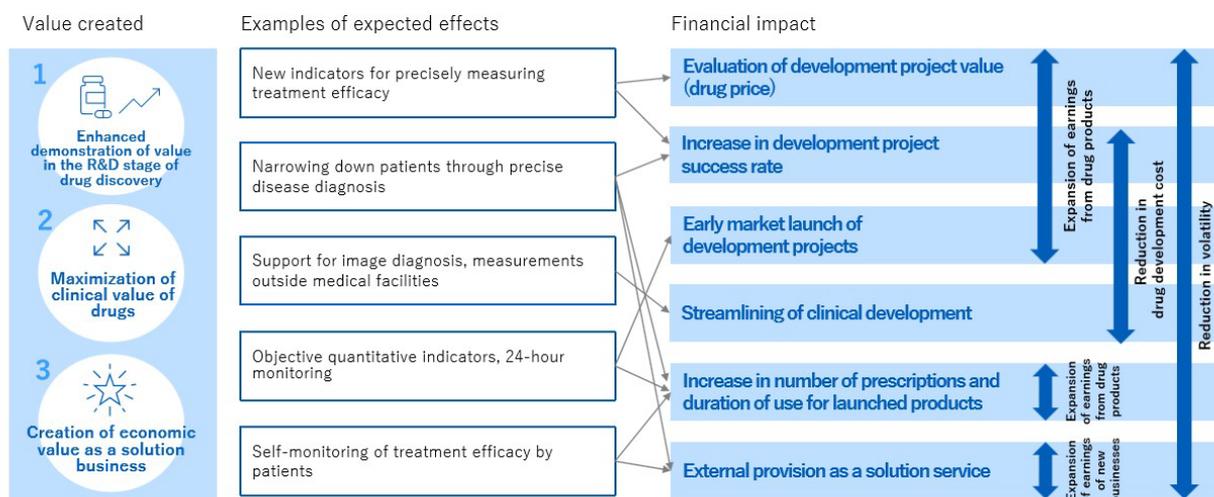
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# Financial Impact of PHC Solutions

Accelerate R&D output and maximization of drug value



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Now, these are three value creations.

The slide expresses five expected effects of the solution and their financial impact. From the above, if we can create new endpoints and indicators to precisely measure the therapeutic effects of pharmaceuticals through solutions, we will be able to accurately evaluate the value of developed products from multiple perspectives.

In addition, if we can precisely diagnose patients' disease conditions and narrow down the list of patients for whom the drug is expected to be effective, we can expect to improve the probability of success in development.

If we can support image diagnosis and enable measurements to be taken outside medical facilities, clinical trials will become more efficient. In addition, the accuracy of data will be improved if indicators that previously relied on subjective evaluation by patients can be replaced with objective quantitative indicators or if 24-hour monitoring can be performed. This can shorten the duration and reduce the size of clinical trials. And we are hoping that the market launch will be accelerated, and the exclusivity period will be extended.

Furthermore, if patients themselves are able to objectively monitor the effects of their treatment, we believe that adherence to medication will improve, leading to an increase in prescriptions, or even revenue from the solution itself.

Overall, we believe that the increase in pharmaceutical revenues and the reduction of development costs, in addition to the direct revenues from solutions, will lead to a significant financial return.

Now that we have talked so much about the concept, I would like to introduce two projects that we are actually working on.

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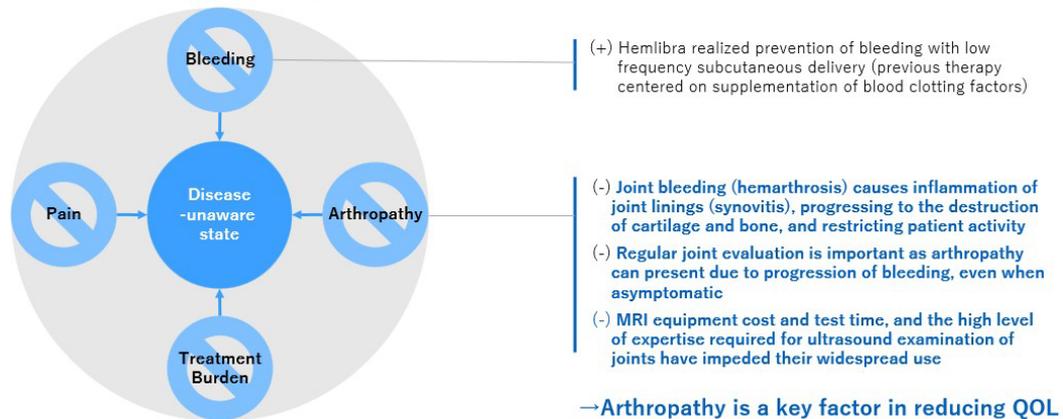
## Case Study 1: Joint Diagnosis Support Solution for the Hemophilia Field (1)

### A bottleneck for improving QOL for hemophilia patients



#### Vision and unmet needs in hemophilia treatment

##### Vision for hemophilia treatment\*



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

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The first will be hemophilia, a core area for CHUGAI.

The goal of treatment for hemophilia is said to be the achievement of a state of unawareness of the disease. The primary challenges for this are overcoming bleeding, arthrosis, treatment burden, and pain. Bleeding has been greatly improved with the introduction of our product Hemlibra, in addition to replacement therapy of blood coagulation factors.

Hemlibra, in particular, is a low-frequency, subcutaneously administered antibody drug that greatly reduces the treatment burden. On the other hand, arthropathy is said to be a major factor in the decline of quality of life. Bleeding in the joints causes inflammation of the synovial membrane, which in the long-term leads to progressive joint destruction and eventual limitation of movement. It is believed that asymptomatic hemorrhage may occur without the patient being aware of it, suggesting that arthropathy may have developed and progressed as a result of the hemorrhage.

Therefore, it is very important to evaluate joints on a regular basis. On the other hand, diagnosis of intra-articular hemorrhage cannot be made frequently with MRI. Also, joint echo requires a high degree of expertise in reading, and we believe that there is a great unmet need here.

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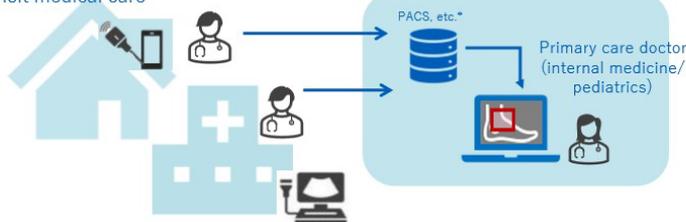


## Case Study 1: Joint Diagnosis Support Solution for the Hemophilia Field (2)

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



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



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.

\*PACS: Picture Archiving and Communication System

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In collaboration with Hitachi, Ltd., we have developed an AI algorithm that visualizes hemorrhage and synovitis lesions in joint echo images to assist the attending physician in reading the images. We are also considering applying this algorithm to images obtained by portable echocardiography, which can be performed in outpatient clinics and home-visit clinics.

If this solution becomes practical, it will reduce the hurdles in the evaluation of hemophilia arthropathy and allow for more frequent diagnosis. This will optimize the treatment of each patient and enable patients to adjust the intensity of exercise themselves, which we hope will lead to a more desirable lifestyle.

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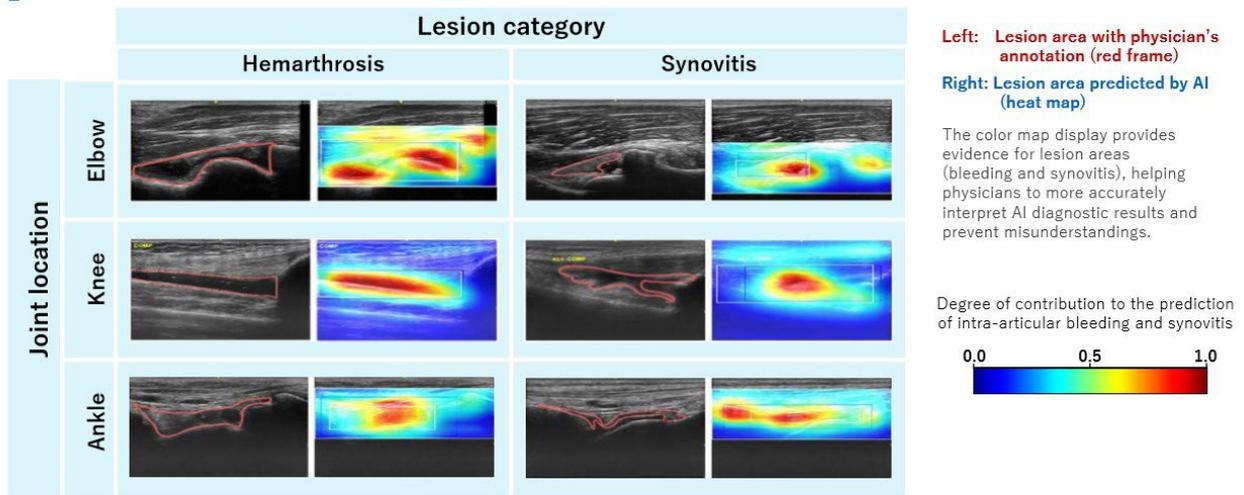
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## Case Study 1: Joint Diagnosis Support Solution for the Hemophilia Field (3)



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



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

- 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](https://www.rpthjournal.org/article/S2475-0379(24)00128-6/fulltext)  
 - 46<sup>th</sup> Meeting of the Japanese Society on Thrombosis and Hemostasis (June 13, 2024)  
 - 66<sup>th</sup> ASH Annual Meeting and Exposition (December 10, 2023)

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Here are the results of the published AI lesion assessment of joint echo.

From the top row, the elbow, knee, and ankle, the echo images of these joints are shown side by side, with 2 images on the left evaluating the hemorrhage in the joint and two images on the right evaluating synovitis. In the combination of two photos, the area circled in red on the left side is the lesion area determined by the specialist, and the color map on the right side is the lesion area predicted by the AI. This means that the detection accuracy is generally above 0.95 for each joint, and we have completed a very accurate AI algorithm and have already applied for a patent.

One of the reasons for the success was that 3,435 images obtained in an observational study conducted by CHUGAI were read and reviewed by one internist and two orthopedic surgeons with extensive knowledge of hemophilia treatment, and the high quality of the data was used as training data for AI.

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# Case Study 2: Solutions in Endometriosis

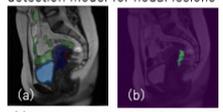


Examples of pain visualization and MRI image diagnostic support

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

<b>Current main treatments for endometriosis</b> <ul style="list-style-type: none"> <li>Administration of hormonal agent to stop menstruation and ovulation</li> <li>Surgical removal</li> </ul>	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.
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**Towards resolving unmet needs in diagnosis and determination of treatment policy**

<b>Current diagnosis:</b> <b>Subjective pain evaluation</b> <ul style="list-style-type: none"> <li>Individual differences in subjective evaluation</li> <li>Efficacy determination through clinical trials also shows variation</li> </ul> <b>Laparoscopic lesion diagnosis</b> <ul style="list-style-type: none"> <li>Definitive diagnostic method. High diagnostic accuracy</li> <li>High patient invasiveness as diagnostic technique</li> </ul> <b>Imaging device lesion diagnosis</b> <ul style="list-style-type: none"> <li>Minimally invasive evaluation method. Ultrasound and MRI as typical examples</li> <li>Diagnostic accuracy dependent on operator experience</li> </ul>	<b>Pain visualization solution</b> <ul style="list-style-type: none"> <li>Wearable device dBM*</li> <li>Enables objective evaluation and 24-hour monitoring</li> <li>Precise pain evaluation enables more accurate understanding (monitoring)</li> </ul> 	<b>MRI image diagnostic support solution</b> <ul style="list-style-type: none"> <li>Accelerate diagnosis by preventing oversight</li> <li>A diagnosis support algorithm that detects the following lesions in endometriosis                             <ol style="list-style-type: none"> <li>nodal lesions</li> <li>adhesive lesions</li> <li>endometriotic ovarian cyst</li> </ol> </li> <li>Early therapeutic intervention                             <ul style="list-style-type: none"> <li>→ Improved QOL by control of endometriosis symptoms</li> <li>→ Securing fertility by early start of infertility treatment</li> </ul> </li> </ul> <div style="text-align: right;">                     Example: detection model for nodal lesions   <p>(a) Segmentation results of lesions and peripheral organs                      (b) Display result showing uncertainty of predicted lesion                      Provided by Preferred Networks</p> </div>
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\*dBM: Digital Biomarker

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Another example, this one is a solution for endometriosis.

CHUGAI is developing AMY109, an anti-IL-8 recycling antibody, for the treatment of endometriosis. AMY109 is expected to exert its anti-inflammatory effect by inhibiting IL-8, thereby improving the disease itself.

The diagnosis of endometriosis is based on the pain felt by the patient, which is confirmed by direct diagnosis of the lesion by laparoscopy to make a definitive diagnosis. Since laparoscopic diagnosis is very invasive, we usually use ultrasound or MRI images for diagnosis, but we believe that there are various unmet needs for both methods.

First of all, as for pain, the patient evaluates the pain by checking a box on a scale of 1 to 10. This will also become an indicator of clinical development, though. We are conducting a project with a US company called Biofourmis to try to somehow quantify this using wearable devices.

I have brought a wearable device, which looks like a simple wristwatch, but it has four sensors: heart rate, skin temperature, skin potential, and a three-axis accelerometer. This is a project to create an algorithm to quantify pain. It's nothing fancy, but this device is FDA 510K certified.

If successful, it will enable objective quantitative evaluation as well as 24-hour monitoring, which will undoubtedly improve the accuracy of the evaluation of disease status and drug effects, instead of the conventional subjective evaluation.

On the other hand, I apologize for the small size of the images, but the diagnostic imaging algorithm to detect nodular lesions and fusion lesions is being developed in collaboration with Preferred Networks, using MRI images acquired in the AMY109 development study.

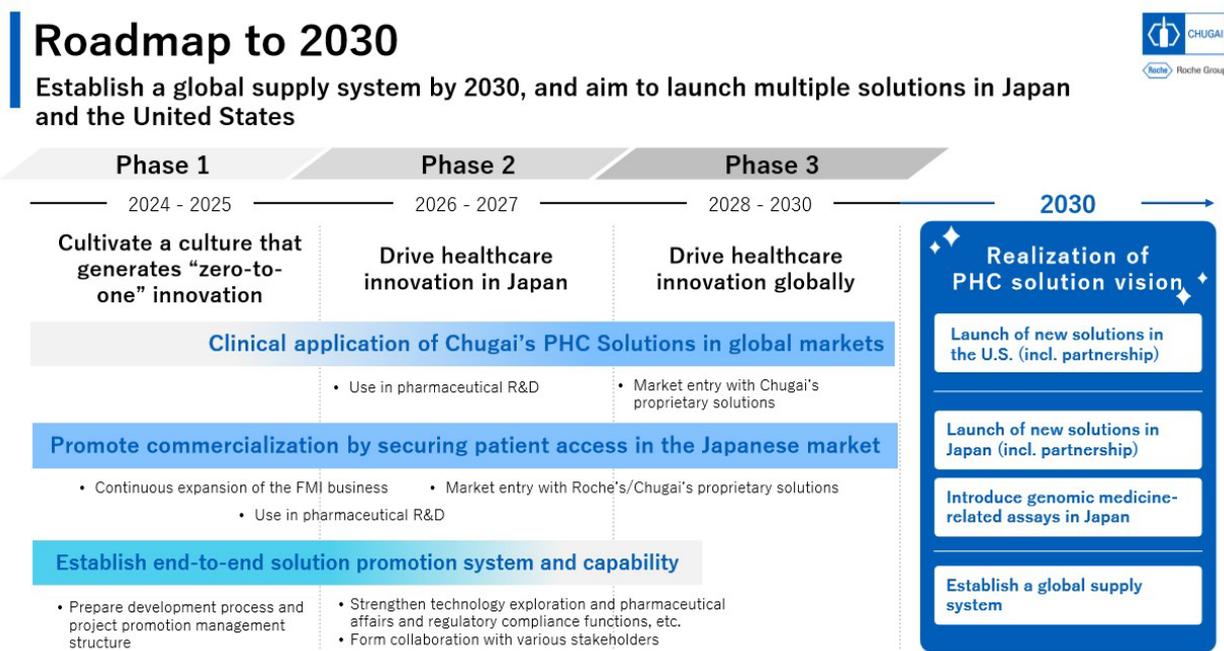
At the moment, the project is progressing in terms of detecting the location of lesions, but in the future, we would like to assess the severity of lesions and even quantify them, thereby enabling us to evaluate the pathological condition and the treatment effects.

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In this way, we intend to take on the challenge of developing solutions in line with the progress of drug development.



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The last slide will be the roadmap to 2030.

I will start from the bottom of the slide. First of all, as I mentioned at the beginning, PHC solutions are different from the pharmaceutical business, and we believe that it is urgent to address everything from the development of a promotion and management system to the establishment of capability.

In particular, we will discuss with companies and startups that have expertise in sensing devices and AI algorithms as components of the solutions.

On the other hand, CHUGAI will strengthen its capability to identify solution needs, search for technologies, promote projects, and establish business schemes based on its capabilities cultivated through R&D and sales of innovative new drugs.

In the Japanese market as written in the middle, we would like to develop our own solutions for our in-house pharmaceutical products, and for pharmaceutical products introduced from Roche, we would like to incorporate PHC solutions developed by Roche, if any, and make them available in Japan.

Of course, we consider F1CDx as one of our solutions, but we would like to further expand our business by expanding our product lineup of cancer genome-related assays and by introducing new assays.

In the global market, which may be the core of our target, especially in the U.S. and the EU, where the pharmaceutical market is large, we would like to develop our solutions for in-house pharmaceuticals and make them available for clinical development and post-launch.

As described above, the market for this solution business is still in its infancy. We will promote the project in an agile manner and grow it into a new business that supports the pharmaceutical industry and provides optimal solutions for individual patients. That’s all from me.

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## Question & Answer

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**Miyata [M]:** We will now move to the question-and-answer session. Onozawa, Head of Corporate Planning Department, and Iijima, Head of PHC Solution Department, are also present for the Q&A session.

We apologize for the inconvenience, but in order to encourage more people to ask questions, we would appreciate your cooperation in limiting the number of questions to two per person.

Please note that the audio of your questions, along with the presentation, will be posted on our website at a later date.

**Kimura [Q]:** My name is Kimura from Nikkei Biotech, Nikkei BP. Since we are allowed to ask two questions, I would like to ask Mr. Fujihara for one question and Mr. Yamaguchi for the other.

Regarding the first point, regarding the PHARMONY system to incorporate patients' voices, I think it is not so difficult to approach patients if there is large patients' groups, but on the other hand, there are cases where there are few patients, rare patients, and few, or no patient groups. Can you tell us about how you pick up the patient's voice in such cases and what you are doing to devise ways to do so?

**Fujihara [A]:** Thank you for your question. We are aware of the points you just pointed out as one of the issues we need to address. One method we are taking is to conduct it in the form of a survey of patients.

There are patient associations such as the All Cancer Federation, Rare Disease Associations, and RENGO, and for each development project, we assign a Patient Engagement Leader, who is in charge of communication with patients, to the development project team. These members communicate with patients on a daily basis and listen to their various problems, which we resolve as internal projects. If we are not able to solve the problem, for example, we will promote it to industry activities or involve other stakeholders. This is what we are doing to work on problem solutions.

**Kimura [Q]:** Thank you very much. I understand very well. Secondly, I would like to ask Mr. Yamaguchi. In your roadmap to 2030, you mentioned the introduction of genome medicine-related assays in Japan, mainly in the area of cancer genomics, and you mentioned the expansion of products and the introduction of new assays. I would like to ask for details on what exactly you intend to achieve.

**Yamaguchi [A]:** Thank you for your question. First of all, in terms of our business, we are expanding our lineup of CDX tests in conjunction with F1CDx, etc. In addition, we are discussing whether DNA alone is sufficient in the future and monitoring to pick up circulating DNA from the remaining part of the cancer, we would also like to offer a lineup of products for blood cancer, which was recently introduced by another company.

On the other hand, as mentioned, there are some obstacles, such as the severe insurance restrictions and the uniformity in the price and reimbursement. I believe that it is necessary to make the assay available at an early stage before the standard treatment and to create a better environment.

**Kimura [M]:** Thank you very much.

**Narita [Q]:** My name is Narita from Nikkan Yakugyo. I also have two questions. With the election last month, the Japanese government structure has changed considerably, and the power relations among the various parties have changed, we would appreciate it if you could tell us again about the ease of lobbying not only in your company but also in general, and what specific activities you have been focusing on recently. Thank you.

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**Fujihara [Q]:** I'm sorry, let me confirm. Is my understanding correct that you are asking about lobbying activities as a business association?

**Narita [Q]:** I'm sorry. Yes. I believe there is an organization that your company is involved with, and I would like to know if there are any activities with such an organization.

**Fujihara [A]:** You mentioned the recent election in the House of Representatives is also quite a big change, it means that how to administer the government will also change in the future. What we in the pharmaceutical industry are most requesting is that the former Prime Minister Kishida, for example, stated at the Drug Discovery Ecosystem Summit on July 30 that the pharmaceutical industry was a key industry that would be responsible for future growth. We are now asking that the Ishiba administration continue such a trend and continue to promote the efforts that have been made so far. I hope I answered your question.

**Narita [M]:** That's fine. Thank you.

**Hyogo [Q]:** My name is Hyogo from Mitsubishi UFJ Trust and Banking Corporation.

Thank you for your explanation. One question is how often you plan to review material issues in the future, and the other is that you have actually reviewed material issues and linked it to KPIs. I think there is a page that mentioned the importance of material issues in terms of the size of impact, etc. In terms of impact, I wonder if some progress has been made in quantification. There are some things that are difficult to quantify, and I think that your Company's KPIs may not necessarily be just quantitative, but could you explain how you quantify these things?

**Yano [A]:** I will answer the question. This is Yano. First of all, regarding the frequency, the establishment was in 2019, so I think four to five years is a good cycle to look at it in terms of monitoring. Of course, we are considering annual reviews in our discussions, but we currently have TOP I 2030 and management targets for 2030, and we have a growth strategy, so if there are any changes, we will make changes accordingly.

Then, in terms of the relationship between the performance indicator and so-called output indicators or KPIs in your second question, as I mentioned at the beginning of the presentation with slides, the most important goal of TOP I 2030 is to double R&D output, and to launch global in-house products every year. These are our challenging targets.

In order to achieve this, we need to consider how our portfolio and other things will look, so I felt that we should annually disclose this R&D index, the number of in-house products created, the number of transitioned in-house products created by Chugai in Japan, the number of global out-licensing projects, and the number of items that have obtained PoC, and I felt that if we could explain how these things would lead to doubling our output or launching a global product every year. Am I answering your question?

**Hyogo [Q]:** I think that is probably the ultimate goal, but in the end, I wonder if these material issues are tied to various things in order to realize it. I guess it is difficult for outsiders to evaluate how the material issues move, is that right? Of course, we can evaluate whether the final output was successful or not, but is it difficult for outsiders to evaluate the process leading up to the final output?

**Yano [A]:** First, we have reviewed the material issues this time and changed the number of material issues from 26 to 16, and we are considering reviewing the indicators for material issues in the future. I would like to discuss how we can present the progress of these material issues to you.

What we are putting together now is an explanation today of how the current related performance indicators that we have already disclosed are linked in the new material issues, and we would like to continue to examine KPIs in line with the newer material issues.

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**Taniguchi [A]:** I'm Taniguchi. I would like to give you some additional information. On page 20, there is a section on the very relevant performance indicators and their material issues. Although these indicators are not directly linked to each of the items, they do have some kind of impact on them. I think that these indicators can be used to indirectly measure the degree of achievement of each of the individual items, and as a large block, I think that this is also a way of reading them.

Although each one is not directly linked to the other, I think that innovative pharmaceuticals and services like these will be linked to the right side, as Yano just mentioned, such as PC transition products, I think that these things will be linked, and although they are on the right in terms of human resource development and growth, they are also indicators that are linked to employee engagement and the rate of fulfillment of highly specialized human resources. I would like to have an opportunity to talk to you as much as possible about the current status of this area and how it is related to the current indicators and how it is being achieved. Thank you.

**Hyogo [M]:** Thank you. I'm looking forward to that, too, and since the word impact has come up in various contexts this time, I think it would be great if you could provide a clear disclosure of that kind of impact. That's all. Thank you.

**Kimura [Q]:** My name is Kimura from Nikkei Biotech, Nikkei BP. Excuse me. Another questioner asked earlier about the impact of the Ishiba administration. Will the Presidential election have an impact in the future in terms of setting strategies and so on? If you have any comments on the Presidential election and the impact by the Trump administration, please comment.

**Fujihara [A]:** I'm Fujihara. Thank you for your question. I think it is an impact of the very high possibility of the Trump presidency. One of the most important things for the pharmaceutical industry is that if Mr. Trump's inward-looking stance leads to the return of production to the US, the supply chain of various pharmaceutical products will be affected.

Another thing is that when Mr. Trump was the former president, he proposed a system like a reference pricing system, where he would look at overseas prices and refer to the cheapest country's price. That policy was not implemented under the Biden administration, but now that we will be back to the Trump administration, I think one thing we need to pay attention to is how that policy will turn out.

Then the other thing is the Inflation Reduction Act, or IRA, which is now in place under President Biden, and what will happen to it under President Trump. Since these areas have a considerable impact on our business performance, we think it is important to keep a close watch on them.

**Taniguchi [A]:** I'm Taniguchi. If I may add a few words, in terms of sales of pharmaceuticals, we export to the US via Roche and sell our products there. What kind of prices and reimbursements will be made there is an important issue that will have a significant impact on our business performance.

We are in the process of gathering various information on this, along with Roche, which has just been mentioned. I believe that we are just now beginning to learn a lot about what kind of policies the new administration will adopt for the health insurance sector. However, we are also aware of the possibility that the IRA under the current DPJ administration will continue in some form or be further strengthened, but in the long term, we believe that we can differentiate ourselves by offering innovative products that meet the unmet needs of patients. I believe that we have a high possibility of gaining an advantage in reimbursement and actual price calculation, by differentiating ourselves from our competitors by offering products that are innovative and meet the unmet needs of patients. So we need to concentrate on that. We are in the process of gathering this information and hope you understand.

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**Onozawa [A]:** To add a little more, you just mentioned the presidential election, but there is no major difference in the direction of the so-called pharmaceutical industry between Republicans and Democrats, so it is not expected to have any impact as a major trend. It is difficult to comment too much on the presidents of other countries, as Fujihara said, but generally speaking, the current situation is that we are not aware of any major trend changes, although the risk is that movement of President Trump is a bit difficult to read.

**Kimura [M]:** Thank you very much.

**Muraoka [Q]:** Hello, this is Muraoka from Morgan Stanley. Thank you.

On page 30, I was looking at this place because I thought it was wonderful that you were working on these things, revising and improving the access to jRCT, the clinical trial information. But... On the other hand, when I want to look at the development status of your product on Clinical Trials.gov instead of jRCT, there are many times when there is no information on Roche-licensed products.

If I would say a little more, I just looked it up again and thought it was what I expected. We still haven't seen any information on the GYM329 obesity clinical trial. If this is a problem for Roche, that would be the end of it, but if Chugai wants to make this kind of clinical trial information accessible to everyone and wants to expand it, I would like to ask you to actively work on this to Roche and make sure that people can see this kind of information. If Chugai has any comments on this point, I would be grateful if you could share them with us.

**Taniguchi [A]:** Taniguchi will answer. Thank you very much. Basically, clinical trials of our products in Japan are one of the most important targets of the projects primarily.

We are aware that it is somewhat difficult to see the situation regarding the products licensed out to Roche. We are wondering what can be done in the future to further raise the sense of challenge in this area with Roche and address it. I hope this answers your question. Is that all right?

**Muraoka [Q]:** Thank you. I'm sure that will be the case, but of course there are lots of competitive reasons, but if Chugai thinks that access to this information is important, I would very much appreciate your cooperation and your appeal to Roche. It is really a request base.

**Taniguchi [A]:** Yes. Thank you.

**Muraoka [M]:** That's all. Thank you.

**Banno [Q]:** My name is Banno from Nihon Keizai Shimbun. Thank you for the presentation today.

I would like to ask Mr. Yamaguchi two questions. About PHC Solutions. You mentioned one, two, and three in the area of value creation, and you said that in general it is difficult to monetize PHC solutions. And you mentioned earlier that you are focusing on number one and number two.

I don't think that just because a drug has been specifically improved in terms of its efficacy, this will necessarily be reflected in the drug price. I would appreciate it if you could explain again how you plan to monetize this PHC solution within the framework of the current situation.

**Yamaguchi [A]:** Thank you. First of all, I am not saying that PHC solutions themselves cannot be monetized. This solution is basically based on the assumption that approval will be granted and that medical fees will be attached to it. However, I think that the medical fees are attached to the medical staff, and I think that the revenue from providing the solution itself is not that large.

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On the other hand, I believe that if, for example, the effectiveness of treatment can be measured precisely, the first and most significant thing is that the success of clinical trials will rise. In particular, as I mentioned earlier, in cases of pain, itching, or mental disorders, patients and medical professionals assess how much the patient's condition has worsened in the clinical trials, so the reality is that we are conducting comparative trials with a very large number of cases. Even so, it is difficult to detect the difference, but if the patients' condition can be measured precisely, I think it will solve a lot of problems.

On the other hand, there are some patients who do well with approved drugs and some who do not, and this is expressed in terms of rates such as efficacy rates. For this, too, if the MOA of the drug and disease, as well as its condition, can be measured more precisely, we can try to narrow down the list to patients for whom the drug is effective in the first place.

Of course, there have been cases in which molecular-targeted drugs for cancer have clearly narrowed down the segment of patients with HER2 abnormalities or ALK abnormalities that have therapeutic effects. There is also the possibility that other things like this will become possible.

In this sense, in the case of drugs, we spend a lot of money on research and development, but whether or not the development candidates that result from the research and development can prove their value in clinical practice and whether or not they are successful in clinical trials largely links to a probability of success, and this is where the impact of returns will be very large.

**Miyata [M]:** Thank you.

With this, we conclude the Sustainability Meeting.

If you have additional questions, please contact Corporate Communications department. The phone number and email address are provided on the last page of the presentation materials.

Please note that a survey will be available on the desk for those in the audience in the venue and on the Zoom for those participating via Zoom. We would appreciate your cooperation in this regard for future reference.

Thank you for joining us today despite your busy schedule. Thank you very much.

[END]

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