Innovation all for the patients



CHUGAI PHARMACEUTICAL CO., LTD.

DX meeting

September 29, 2023

Event Summary

[Company Name] CHUGAI PHARMACEUTICAL CO., LTD.

[Company ID] 4519-QCODE

[Event Language] JPN

[Event Type] Analyst Meeting

[Event Name] DX meeting

[Fiscal Period]

[Date] September 29, 2023

[Number of Pages] 62

[Time] 13:00 – 14:31

(Total: 91 minutes, Presentation: 61 minutes, Q&A: 30 minutes)

[Venue] Webcast

[Venue Size]

[Participants]

[Number of Speakers] 5

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Presentation

Miyata: Thank you very much for attending the Chugai DX meeting. 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 at the same time. The agenda for today's meeting is shown on the venue screen, on the web screen and on the first page of the presentation materials. We will follow the agenda.

Please note that the number of speakers has increased by one from the previous announcement, with the addition of Mr. Keisuke Ohara, Head of the IT Solution Department.

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.

Now, Ms. Shisai will explain the progress of CHUGAI DIGITAL.

Ms. Shisai, please go ahead.

Shisai: Thank you very much for taking time out of your busy schedules to join us today. My name is Satoko Shisai, Head of Chugai's Digital Transformation Unit.

At the beginning of this meeting, I would like to talk about the progress of CHUGAI DIGITAL.



Top Innovator 2030

◆ Realization of Chugai's "Envisioned Future" in 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 in globally to think they can create something new by partnering with Chugai



Role model for the world

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

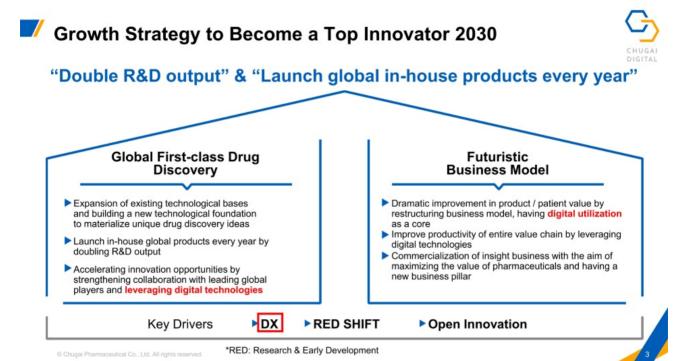
Our definition of "Top Innovator in the healthcare industry"

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In collaboration with Roche, we will continue to place "innovative new drugs" at the core of our business, while aiming to become a leading innovator in the global healthcare field, where a diverse range of players, not limited to pharmaceutical companies, are taking on the challenge of innovation.

First, here is the image of the top innovator we are aiming for in 2030, and a diagram of what kind of top innovator we are aiming for in our TOP I 2030 growth strategy.

Naturally, as a pharmaceutical company, we must continue to create new drugs expected by patients around the world. Or, to have people expect that something new will happen through co-creation and collaboration between Chugai and various players around the world, not only in the healthcare industry. And we want to be a role model for the world.



Against this backdrop, in 2021, we drew up a growth strategy called TOP I 2030, which aims to realize the image of a top innovator in 2030.

What we aim for here are these two in the middle. The first strategy is Global First-class Drug Discovery. And to maximize that investment, we will make structural changes to our futuristic business model. By doing so, we hope to achieve the very high goals mentioned above: doubling our R&D output and launching global inhouse products every year.

One of the three key drivers of the TOP I 2030 vision is DX, or digital transformation. In the Digital Transformation Unit, we are promoting DX throughout the Company.

CHUGAI DIGITAL VISION 2030



Transform our business by using digital technologies to make Chugai a top innovator in the provision of society-changing healthcare solutions

Transform our business

- Provide innovative drug products continuously by leveraging digital technologies.
- Greatly streamline all value chains.
- Create frameworks for providing innovative services.
- Change employee awareness and organizational structure and customs at Chugai.

Society-changing healthcare solutions

- Provide optimal personalized healthcare suited to individuals.
- Produce high QoL throughout life through ultra-early diagnosis, prevention, and treatment.
- Bring about social assurance programs sustainable even in shrinking and aging societies.



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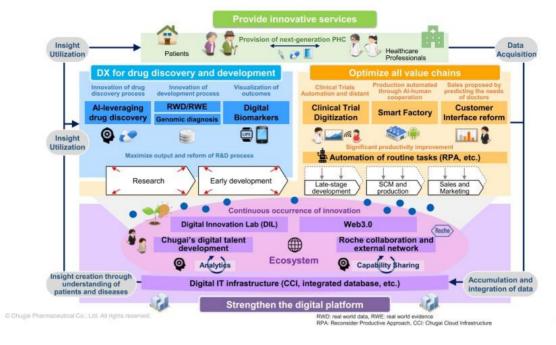
In 2020, when TOP I 2030 was announced, we showed CHUGAI DIGITAL VISION 2030 as DX. The vision is to transform Chugai's business by using digital technologies to make Chugai a top innovator in the provision of society-changing healthcare solutions.

Business transformation includes, of course, the provision of innovative new drugs, the streamlining of all value chains, creation of innovative services, as well as the change in employee awareness and organizational structure and customs at Chugai to create those things.

By aiming for those things, we would like to provide society-changing healthcare solutions as shown on the right: Providing optimal personalized healthcare, producing high QoL throughout life, and contributing to sustainable social assurance programs. We have been proceeding with this vision since 2020.

Overall Picture of CHUGAI DIGITAL VISION 2030





This is the overall picture of CHUGAI DIGITAL VISION 2030 that we often use for explanation. This picture depicts where we are focusing our efforts and what we are trying to do.

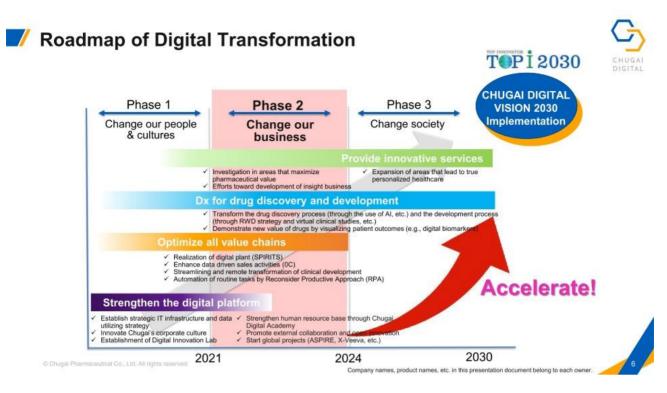
One of the three strategies, the blue part, is DX for drug discovery and development, meaning exactly the kind of digitization that supports our core business: Al-leveraging drug discovery, the use of real-world data, and the development of digital biomarkers, as I will discuss later.

As for the value chains, there are four major pillars in the value chains of a pharmaceutical company: research, clinical development, manufacturing, and marketing. The idea is to digitize all of these one by one and optimize all value chains.

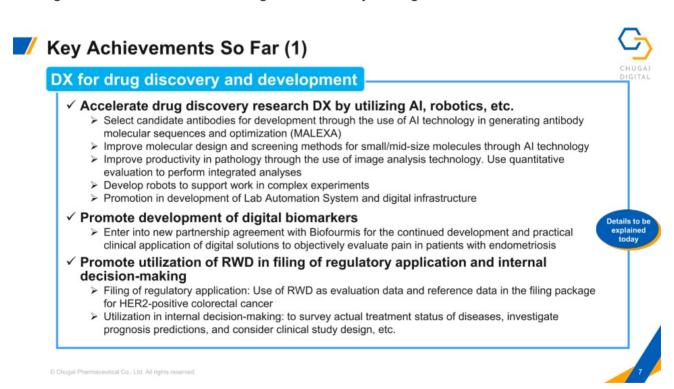
We are also working to automate various routine tasks, including corporate ones, using RPA throughout the Company.

Then, of course, we will be talking about the digital platform at the bottom, the digital IT infrastructure. This digital infrastructure, or the academy for human resource development, which we call the Digital Innovation Lab, is also tackling initiatives to digitize various ideas of our employees and apply them to actual business operations.

In addition, as the latest topics, we would like to mention Web 3.0, or ChatGPT, and generative Al.



According to the roadmap of DX, we started this initiative in 2020. Now, in 2023, we are shifting from building a foundation in Phase I to utilizing it to make a major change in our business.



I would now like to discuss our main achievements to date.

The first is the discovery of innovative new drugs through the use of digital technologies. As you can see here, we are accelerating DX in drug discovery research by utilizing AI and robotics.

As I mentioned at the beginning, we continue to use MALEXA, the machine learning system, for antibody optimization. At present, we apply AI technology not only to antibodies, but also to small/mid-size molecules.

As for image analysis, we have been actively using it since the beginning in 2020 to achieve significant efficiency in productivity.

Also, robots that assist in complex experiments are shown to visitors to the Chugai Life Science Park Yokohama, which opened this year. As the researchers work, we have realized an automation process in which the robots bring various reagents and other items to the researchers.

We have also built a digital infrastructure that automates not only robots, but also the sharing of knowledge throughout the institute, or workflows, processes, and other such things.

As for the development of digital biomarkers, I will not discuss individual projects today, but there are less than 20 projects that are utilizing these digital biomarkers. Later, Dr. Ishii will talk about the insight business, and he would also like to talk about one case study, a digital biomarker for pain measurement, and the subsequent process.

In addition, in relation to approval using real-world data, or RWD, we are actively using RWD as evaluation data and reference data in the filing package for HER2-positive colorectal cancer in various interactions with the authorities for regulatory applications.

In addition to the applications for approval, RWD is also used for early- and late-stage clinical trials, clinical trial design, early-stage prognosis predictions, and post-marketing surveillance. RWD is being utilized in a wide range of areas across different divisions.

Kev Achievements So Far (2)



Optimize all value chains

- ✓ Promoting initiatives towards smart factories
 - Equip Ukima Plant with the following functions.
 - (1) Automation and visualization of work plan drafting
 - (2) Efficient assignment and utilization of human resources throughout the entire plant
 - (3) Use of smartphones to enable remote support and tamper-proof image recording tools
 - > Promote deployment to Fujieda Plant and Utsunomiya Plant

✓ Promote updating of customer engagement model

- Support sales, safety, and MA activities with a comprehensive platform that integrates customer databases and information on various solutions, and a decision-making support engine that utilizes AI. Accelerate improvement of operation results
- ✓ Digitization of clinical trials: Promotion of DCTs
 - > Start decentralized clinical trials (DCTs) incorporating visiting nursing and telemedicine into ordinary clinical trials in the US
- ✓ Promote Reconsider Productive Approach (RPA) efforts
 - Initially aimed at reducing workload by 100,000 hours by 2023, but achieved 150,000 hours workload reduction by the end of 2022

Next is optimizing all value chains. I'm going to rush because my time is limited. As for the initiatives towards smart factories, which started in 2020, the first phase is underway at the Ukima Plant.

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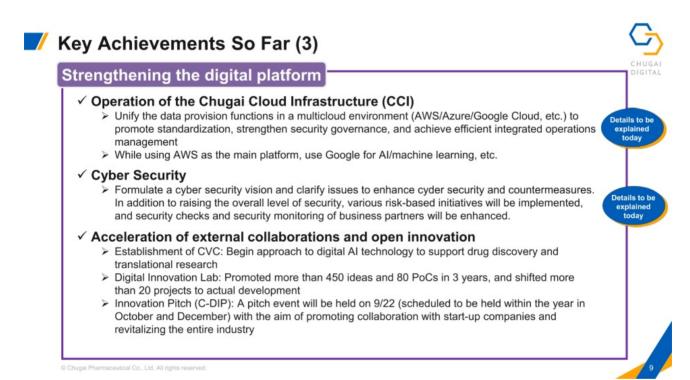


We have realized a system that allows us to drop down from production plans to actual work plans and instruct or communicate the plans to individual workers, staff, and employees. Roughly 200 to 300 factory floor employees are now using this system. In addition to planning systems, we also offer various training or remote tools to streamline the process.

As I have mentioned several times, the customer engagement model also utilizes an integrated database that includes customer data and external data to support decision-making with the help of AI. This is shared not only by the marketing & sales division, but also the other two of the three delivery divisions as we call, i.e. the medical affairs division and the drug safety division.

Then there is the digitization of clinical trials. Recently, we have succeeded in implementing a system called Decentralized Clinical Trial, which allows patients to participate in clinical trials from their own homes, naturally utilizing various home nursing services and online services, in early clinical trials.

As for RPA, or Reconsider Productive Approach, I mentioned it about two years ago. We achieved a workload reduction of 150,000 hours by the end of 2022, exceeding our initial goal.



As for the digital infrastructure, today, Mr. Ohara will talk about building a multi-cloud, which is called Chugai Cloud Infrastructure.

There will also be a mention of various initiatives regarding cyber security.

In terms of external collaborations and open innovation, we are also making progress on the establishment of a CVC, which we announced this year. As for the Digital Innovation Lab, the number of internal ideas is currently 450, which is a very large number. Some of them have been shifted to actual development.



Key Achievements So Far (4)



Strengthening the digital platform

✓ Launch & promote ASPIRE project

Introduction of state-of-the-art global standard processes and next-generation core business infrastructure (ERP), and promotion of company-wide operational process and organizational

✓ Promotion of data strategy

Accelerate the establishment of a governance/control system whereby anyone who needs to use data can easily find and obtain that data thanks to the establishment of an environment in which the desired analysis can be performed conveniently, together with the FAIR + culture/system

√ Launch of Web 3.0 initiatives

▶ In October 2022, our company's philosophy on Web 3.0 was announced as a Point of View. We will aim for new innovations by utilizing "DAO," "DID," "NFT/FT," etc., based on blockchain technology

Promotion of utilization of generative Al

- > ChatGPT: Company-wide use started in August after various risk evaluations and guidelines were formulated
- Acceleration of utilization for more advanced operations and promotion of evaluation of various types of generative Al



And then there is the ASPIRE project. We are introducing the next-generation core business infrastructure (ERP), which is a very heavy task, but we are now working with Roche on the project to replace the infrastructure by the end of 2026, hoping for a successful result.

As for the promotion of data strategy, Mr. Kanatani will explain today data utilization in terms of data-driven management and Web 3.0 initiatives.

In addition, we have been using generative AI, ChatGPT, which has been in full-scale use throughout the Company since August. Various ideas have been raised within the Company, and we are currently building use cases, which will be explained by Mr. Kanatani, including what kind of use cases are available.



DX Brand: Selected as Grand Prix and Platinum Company



- ♦ The only pharmaceutical company selected for 4 consecutive years since 2020
- In 2022, Chugai was selected to receive the "DX Grand Prix" as "a company that leads the digital era in a manner that transcends the framework of its industry"
- ♦ In 2023, Chugai was selected for the "DX Platinum Company 2023-2025" as a company that has continued to pursue outstanding DX initiatives since the inception of the system



Finally, with regard to the DX brand, thanks to everyone's support, this year we were selected as one of three platinum companies, and we received that prize for the fourth consecutive year.

That is all from me. I would appreciate any questions later. Thank you very much.

Miyata: Thank you very much. Next, Mr. Ohara will explain the multi-cloud strategy and cyber security strategy as part of the three initiatives to strengthen the digital infrastructure.

Mr. Ohara, please go ahead.

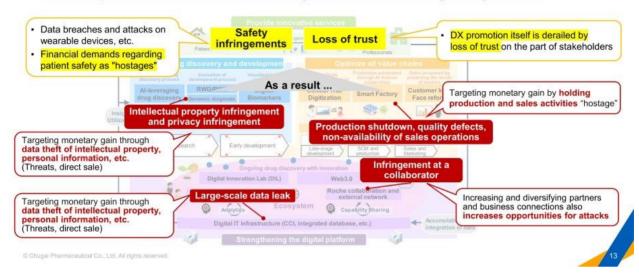
Ohara: Hello, everyone. My name is Keisuke Ohara from the IT solutions department. I would like to explain our multi-cloud strategy and our cybersecurity strategy as part of our efforts to strengthen the digital infrastructure.



Overall Picture of CHUGAI DIGITAL and Security Risks



- ♦ It will be essential to improve comprehensive security capabilities involving all business units
 - Overall picture of CHUGAI DIGITAL security risks that could be targeted by attackers



First of all, I am afraid that this slide is very busy but, this is a mapping of possible security risks, being added to the picture of Chugai DX that was explained earlier.

As you may know, we are an R&D-oriented pharmaceutical company and handle personal information such as intellectual property information and genome information, so there are risks of infringement or leakage of such information.

Also, since we are in the manufacturing industry, I wonder if supply chain risks could be considered. Furthermore, as we move forward with DX, I believe that security measures should be applied to the entire value chains, from research to development, production, and sales, and that formulating company-wide security measures is an urgent issue.

Cyber Security Vision



 Through internal and external environmental analyses, including CHUGAI DIGITAL VISION 2030, create a "vision and strategy" for cyber security by 2030

CHUGAI CYBER SECURITY VISION 2030

Become a cyber security leader to support the achievement of top innovator status in the healthcare industry

Organizational management	 □ Construct a companywide governance system with a robust monitoring/escalation and feedback loop □ Construct a system that supports business and enhances security by having business and IT coordinate while retaining high degrees of specialization
People/Culture	 □ Foster a security culture so that all employees throughout Chugai Global consider "Security First" to be a matter that concerns them personally □ Disclose a commitment to security in an outward-facing, proactive manner
Technology	□ Construct a highly secure IT infrastructure base that enables secure use of data □ Achieve flexible and robust IT security to accommodate ecosystem expansion and change

In light of these internal and external conditions, we created CHUGAI DIGITAL VISION 2030 in 2020, and we have also formulated a vision for cybersecurity.

As it says here, we will "become a cyber security leader to support the achievement of top innovator status in the healthcare industry," which expresses our will to become a leading company in cyber security as well.

To achieve this vision, as shown below, we are in the process of drawing up a roadmap for the realization of the ideal image from the three perspectives of organizational management, people/culture, and technology, and are steadily promoting the roadmap to achieve this goal.

Today, I would like to introduce a few specific initiatives regarding organizational management at the top of this list.

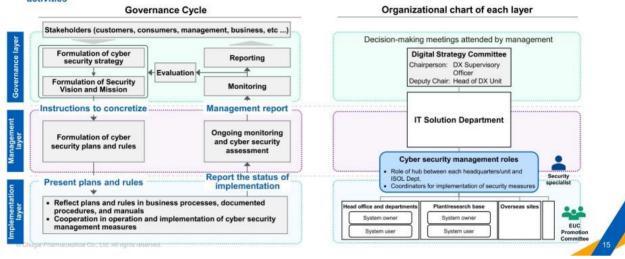


Establish a Cyber Security Management System





- Construct a system to grasp security management information and implement vulnerability management in a timely and comprehensive manner
- Assign an officer to act as coordinator of the headquarters and bases and issue instructions and requests related to security
 Report the results of security monitoring to the management every quarter and connect them to additional improvement activities



After the visioning process, we immediately started working on this. First, we established a security governance structure. We, the IT solutions department, are taking the lead in establishing such a system where information is communicated to all offices or organizations and then reported back to us.

We have also established a process to report this governance status to management once a quarter, i.e. report to the Digital Strategy Committee, which is joined by all department heads.

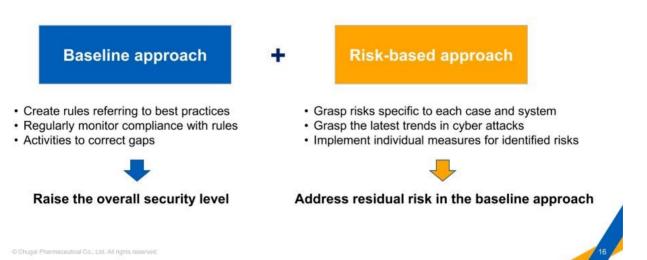
With the establishment of such a system and process, I believed that a PDCA cycle has been realized since the status of security measures, which were previously quite opaque to management, can be communicated on a regular basis, and these reports lead to improvements.

It has been two and a half years since this framework was established, and I feel that it has fostered a healthy sense of crisis regarding cyber security.

Approach to Security Issues



 Gain a comprehensive grasp of information security issues by combining 2 approaches: "baseline" and "risk-based"



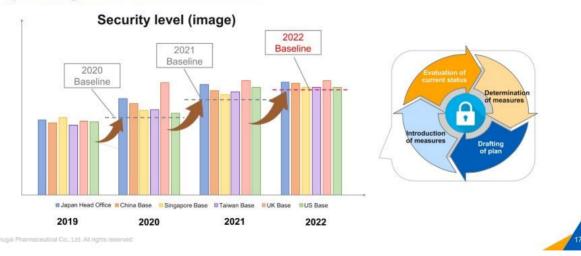
Next, I would like to introduce our approach to the security issues.

Here are two approaches: the baseline approach and risk-based approach. The baseline approach is designed to raise the overall security level. The risk-based approach is to address the residual risk that cannot be handled in the baseline approach. We are taking a stance that comprehensively addresses the security issues on these two approaches.

Baseline Approach



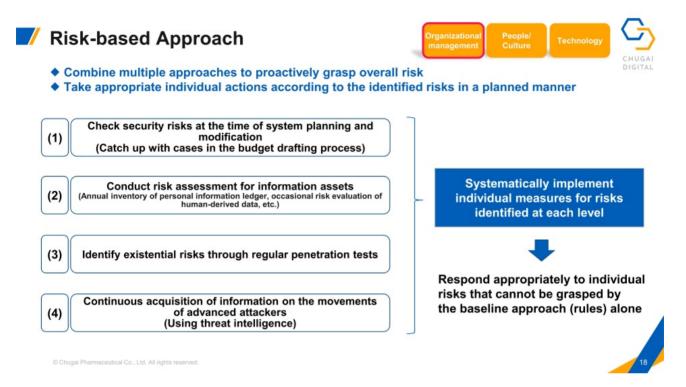
- Each site's security level is scored annually against the best practice collection
- Elevate the security level of the entire Group by establishing a baseline (security goals for each fiscal year) for plants, research laboratories, and overseas bases and planning and implementing various measures to achieve it



I would like to introduce the baseline approach in detail. There is a collection of best practices for security measures provided by a security vendor. We ask all of our business sites, including overseas ones, to

evaluate their situations against this best practice collection and score the maturity and other points of their security levels. Based on the results of the scoring, we are working to raise the overall level of security of the entire Group by determining how far we should aim to go in the following year.

By utilizing this framework, I believe we are now able to compare ourselves with other companies and see where we stand.



Next is the risk-based approach. I won't go into detail, but we have put in place the four measures as listed here to expose and address the risks.

The first measure is to check security risks at the time of system planning.

The second is annual inventory of the personal information ledger. We conduct risk assessment of the information assets, conduct periodic penetration tests, and utilize threat intelligence to identify what risks exist within the Company and take measures to address them.



Business Partner Security Initiatives



- ♦ Check response to the security risks of business partners from 2 viewpoints: "security system/maturity level" and "technical vulnerability"
- ♦ On a trial basis, implement for about 70 of our important business partners

	Details of check	Frequency of checking
Check of security system and maturity level	Confirmation of the status of acquisition of certification such as ISMS* Audit by our company, using checklist	At the start of business + Periodically (e.g., annually)
Check of technical vulnerabilities	Use of security rating services Use of threat intelligence services Use OSINT** to check from the perspective of attackers	Occasional checks, as needed (Routine continuous monitoring)

*ISMS: Information Security Management System **OSINT: Open Source Intelligence

Last year, we concentrated on security checks for our business partners. This is what we were doing.

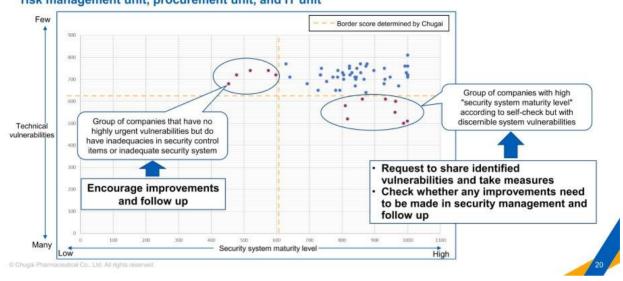
I believe that every manufacturing company feels the threat of supply chain risk from ransom attacks.

We have the risk compliance department that manages business continuity. We worked with them to identify important business partners and conducted checks on the maturity of their security systems and technical vulnerabilities for about 70 companies. We actually did this using PoC last year.

Business Partner Security Initiatives (Results)



Take action based on the results for "security system/maturity level" and "technical vulnerability is lt will be necessary to establish a system for checking in cooperation with the business unit, risk management unit, procurement unit, and IT unit



Here are the actual results. In the upper left of the four quadrants, there are the companies which answered that their security systems are inadequate. We encouraged them to improve their systems. In the lower right corner, there are companies with discernible system vulnerabilities. We also asked them to take improvement measures.

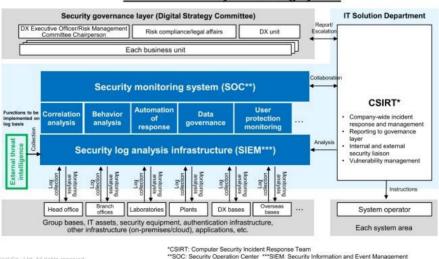
Upgrading of Security Monitoring





◆ Promote to upgrade SOC/SIEM that is central to proactive security response

Vision for security monitoring system



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Also, I don't think security is the only way to manage third parties regarding risks. Since various departments are managing them, I feel that there are a few issues to be addressed in terms of improving the efficiency of the management. As noted here, we are working with the related units this year to develop a cooperative checking system.

The next one is a bit more technical, I'm afraid. It is about the development of the IT side of the system. Our digital infrastructure is constantly changing and expanding with the introduction of new cloud services, the use of external partners, and so on.

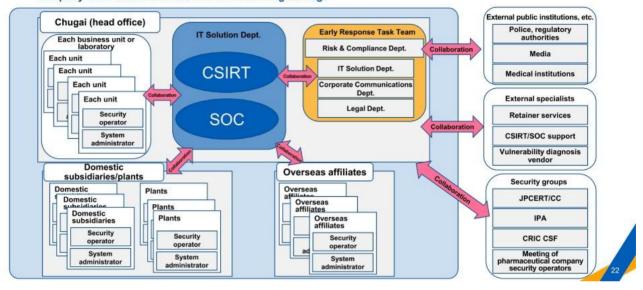
We are working to enhance our SOC system, which properly monitors the latest environment, and our security logging infrastructure to detect such risks more proactively.

Cyber Security Response System



Cooperate and share information within and outside the company in preparation for emergency

In the event of an emergency, promptly set up a task team for early response and take company-wide action with the aim of minimizing damage



Finally, there is the system to prepare for emergency. It is a system in case of cyber-attacks. We manage cyber risk as one of our business continuity risks, just as we manage earthquake, typhoon, and other disaster risks.

From this perspective, when a cyber-attack breach is detected, we will establish an early response task team in close cooperation with the department in charge of BCP management.

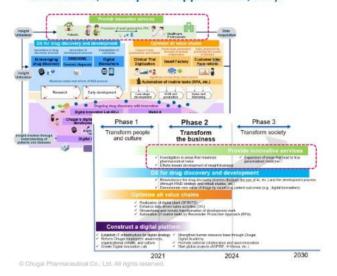
As shown on the right side, we have also established a system that enables us to constantly update the latest information through close information exchange with public institutions, external specialists, and security groups on a regular basis.



Future Theme: Digital Service Security



◆ It will be necessary to establish a security system that anticipates the provision of digital services to patients and healthcare providers (automatic drug delivery devices, digital biomarkers, smartphone applications, etc.).





I have explained the measures we have taken so far, and I think that digital service security is one of the themes we are going to tackle going forward.

Toward 2030, I think that our Company will be working on the top part in green, solving social issues in healthcare, and we may provide digital services for such patients and medical professionals.

In providing such services, we have developed a framework for the protection of our own information, and we would like to develop measures to protect users moving forward.

Why will the Cloud be Necessary?



6 + 1 benefits of taking advantage of the cloud



I would like to continue by introducing a little bit about the multi-cloud strategy.

The first thing we describe here as the need for our multi-cloud strategy to support the acceleration of our DX is why we need the cloud. I would like to briefly explain this, as I am sure you are all aware of.

With the recent advances in technologies, there are various advantages listed here compared to the socalled on-premises environment, where you build your own servers. Recently, from the viewpoint of environmental friendliness in the middle of this, we would like to further promote the use of this cloud.



Why is a Multi-cloud Strategy Necessary?



Leveraging the advantages of multi-cloud

Niche services/ Strengths and weaknesses

A mixture of public cloud services that are carefully selected allows us to access featured services of the respective cloud vendors and niche or advanced services that are not available from other cloud services

Mitigation of vendor lock-in and geopolitical risks

A mixture of public cloud services that are carefully selected can help mitigate or reduce the risks of vendor lock-in. These risks include potential future price increases, service discontinuation by cloud vendors, as well as geopolitical risks that may lead to service outages and delivery delays.

Managing the drawbacks of multi-clou

Measures to simplify operations

Multi-cloud environments are often criticized for their complexity and increased operational burdens. However, when the same vendor handles both the design and operation, it allows for standardized and consistent operations without adding unnecessary complexity.

Also, the use of integrated automation management (IaC products) allows us to reduce operational burdens

Solution for increased costs

Multi-cloud environments do come with disadvantages, such as increased costs from not being eligible for volume discounts. However, by taking advantage of the Roche Group's blanket policy, we have reduced the costs.

Also, by adopting the integrated cost management (FinOps products), we can collectively manage costs across multiple clouds, minimize expenses by adjusting, suspending, or deleting resources while comparing costs among cloud services.

Next is the reason why a multi-cloud strategy is necessary. Multi-cloud is the use of multiple cloud infrastructure services for the cloud infrastructure as we call it.

There are advantages of this, as you can see here in blue. Each cloud service has its strengths and weaknesses, but we want to make sure that we use the strengths in any of these services.

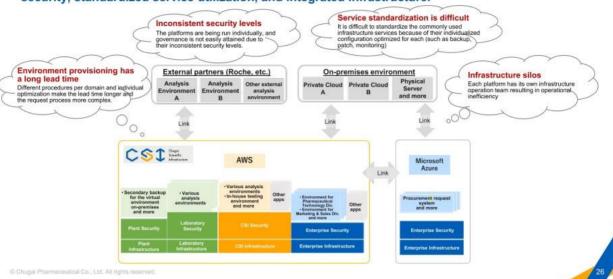
As mentioned below, I think the multi-cloud will avoid vendor lock-in and geopolitical risks such as the inability to use such services in some countries.

On the other hand, there are also disadvantages. As written in this yellow section, our multi-cloud strategy is to address operational complexity and cost increases. This is our company's multi-cloud strategy.

Utilization and Challenges of our Cloud Infrastructure



While we've pursued various measures for DX individually, further advancement of DX at an expedited pace should consider aspects like faster environment provisioning, enhanced security, standardized service utilization, and integrated infrastructure.

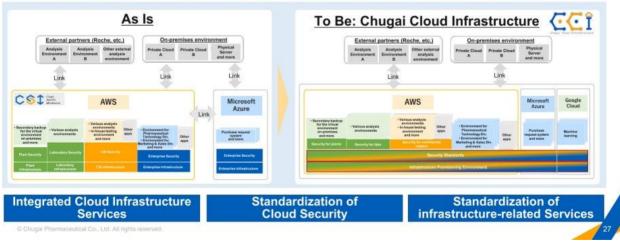


In fact, we have been using cloud services significantly. Until now, each project had its own individual optimization, leading to problems like long lead times for server environment delivery, varying levels of security, and some redundancy in operations.

Overview of the CCI (Chugai Cloud Infrastructure)



- Start building the next-generation Chugai cloud infrastructure (CCI) by utilizing the knowledge of CSI construction
- Efficiently integrate the enterprise system platforms that have been configured on third-party cloud environments
- Centralize cloud infrastructure features for enhanced standardization and security governance
- Continuously improve and extend functionality to keep pace with technological advancements



In this context, we launched the Chugai Cloud Infrastructure, or CCI, last year to address these issues.

The concept is to create a large, secure, and well governed ship-like structure while utilizing the multi-cloud infrastructure.

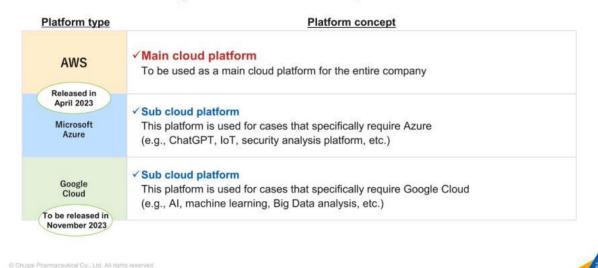
In terms of security, since we are dealing with medical information, there are guidelines for businesses that handle medical information to properly protect such information. We call them the 2G3M, or the two guidelines from three ministries, and we are taking our measures with reference to the 2G3M.

We have launched the concept of putting all value chain systems and applications on the large, robust, and optimized ship like this.

Usage Guidelines for the CCI (Chugai Cloud Infrastructure)



Chugai Cloud Infrastructure (CCI) uses AWS as the main cloud platform, with Microsoft Azure and Google Cloud as the sub cloud platforms.



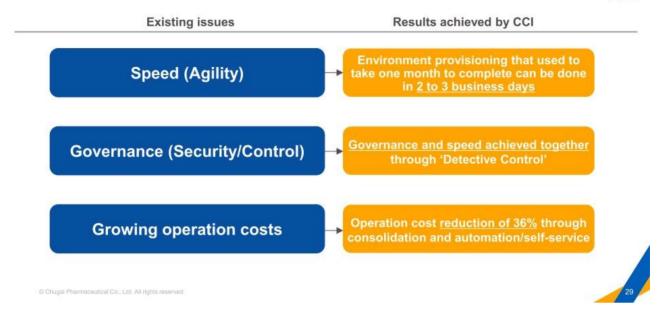
In fact, we made progress on the AWS standardization in April of this year, and then started to standardize Microsoft Azure, and now we are working on Google Cloud standardization, which we hope to release in November of this year.

This shows the usage guidelines for the multi-cloud at the Company as I have just explained. We are considering using AWS, which we are already using extensively, as our main cloud platform, with Microsoft Azure and Google Cloud as sub cloud platforms, while taking advantage of the features and strengths of each one.

In particular, ChatGPT, which I will explain later, runs on Microsoft Azure. As for Google Cloud, we would like to utilize Google's strong machine learning and big data analytics, especially in the area of research.

Effectiveness of the CCI (Chugai Cloud Infrastructure)





This will be my last slide. This describes the effectiveness of the introduction of the CCI. With the introduction of this CCI, we have achieved both speed and governance while leveraging the respective strengths of the multiple cloud services, and have also reduced operational costs.

Going forward, these cloud services are expected to continue to evolve as technology advances. We believe that the environment in which such innovative services can be used quickly will contribute to the further acceleration of Chugai's DX.

That is all from me. Thank you for listening.

Miyata: Thank you very much. Next, Mr. Kanatani will explain initiatives for the use of generative AI and the Healthcare x Web 3.0 initiative.

Please go ahead.

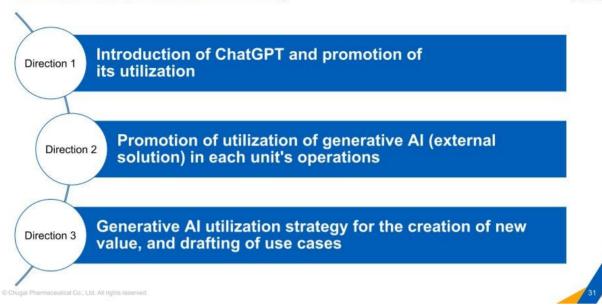
Kanatani: Hello, everyone. My name is Kazumitsu Kanatani, Head of the Digital Strategy Department. Thank you in advance today.

I would like to start by informing you of our efforts to utilize generative AI, followed by Healthcare and Web 3.0.

Promotion Policy for 2023



♦ 3 directions to be promoted for the time being



First, I will talk about generative AI. We are aware that generative AI gained considerable momentum at the beginning of this year, and we naturally intend to be proactive in Direction 1: Introduction and Utilization of ChatGPT, which is representative generative AI, within the Company.

In addition, as mentioned in Direction 2, each business department performs quite sophisticated operations, and there are many service providers that offer AI and other services that are suitable for these operations. We would like to make active use of such external resources.

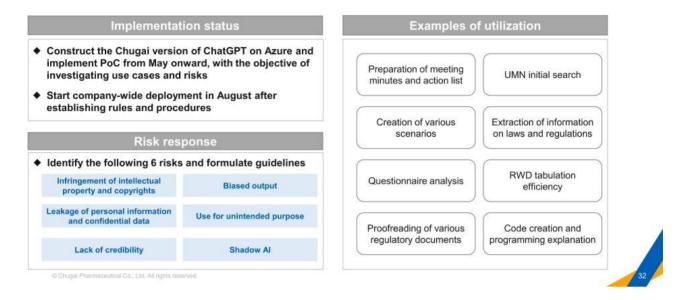
We think Direction 3 is most important. Since our core business is drug discovery, we have been thinking since the beginning of the year about the need for using not only large-scale language models, such as those represented by ChatGPT, but also the entire generative AI for drug discovery.



ChatGPT Utilization Status



 Create infrastructure within the internal environment, confirm use cases through trials, and promote company-wide utilization from August onward after formulating guidelines



First, I would like to share with you how ChatGPT is being utilized.

This year, we created the infrastructure within the internal environment and a limited number of members conducted trials. After we confirmed use cases through the trials, we promoted company-wide utilization from August onward after formulating guidelines. Currently, we have prepared a situation where all employees can take advantage of this service as long as they are registered within the Company.

In putting these things in place, I think it is necessary to respond to the risks mentioned below, as is often said, and to make sure that these areas are addressed.

Since we are a pharmaceutical company, we must not infringe on intellectual property, etc. In addition, since personal information is handled, our core concept is to prevent such information from being leaked by setting guidelines to ensure that such information is not misrepresented and to raise the literacy of each employee.

/ Initial Use Cases



 Develop a platform for utilizing internal and external data and encourage diverse usages of data beyond text

Use case details

Retrieval of paper and abstract summary

- Auto-search on scholarly paper databases using specific keywords
- Summarize the abstract of paper
- Share the abstract along with paper details (such as title, author, sources, abstract, link)

Streamlined programming

- Automatically generate code in Python or R to refine coding and streamline programming tasks
- Input error-containing code in Python or other languages and display suggestions to correct the identified error.
- Input code in Python, VBA, or other languages to identify the content and structure

Analysis of various text data

- Input survey results, including those from Google Forms, into GPT for analysis, which covers the entire process from comment aggregation/analysis to solution drafting
- Based on knowledge compiled internally along with written text for a task, create structured data (e.g., duration, root cause classification, impact, solutions, etc.)

Future usage Various internal data (Contract and privacy info needs strict control)

Various external data

Image and other non-text data



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We have picked up some of the many initial use cases in the process of deploying ChatGPT within the Company.

One is written on the far left, retrieval of research papers and abstract summaries. Nowadays, there is a lot of information out there, and I think we have come to a time when it is difficult to collect a great deal of information just from papers and peruse them as a researcher. If these data could be automatically obtained, summarized, and fed back to our researchers on a daily basis, it would improve operational efficiency, so we are working on such use cases as needed.

We recognize that this is an area where the researchers, data scientists, and engineers in the Company are becoming much more productive due to the efficiency of programming.

ChatGPT is very language-specific, so it can be used to analyze what people have had to follow with their own eyes, such as the results of questionnaires or qualitative evaluations, by using this kind of language model and we are formulating the basis for subsequent measures by using it.

We have presented only a limited number of use cases. We are now in the process of prioritizing and organizing what can be used in all value chains and organizations within the Company and where to start.



Idea Types Frequently Requested in ChatGPT and Direction of Realization



- Promote utilization of ideas that can already be implemented
- Cognitive searches, etc., where the infrastructure is best considered by the entire company should be executed chiefly by DXU

Already feasible	Streamline with ChatGPT and Microsoft Copilot	Preparation of draft emails	Preparation of draft meeting minutes	Preparation of draft codes
		Translation/proofreading	Create drafts of recruitment guidelines and questions	Summaries of papers
Handle by DXU + each unit	Enable with "Add your data" function	Simplification of SOP search and document preparation	Confirmation of how to use systems, equipment, software, etc.	Responding to various inquiries (Chatbot)
		Preparation of draft internal and external explanatory materials and educational materials		
rastructure to be onsidered by DXU	Realize by combining ChatGPT with other systems	Cognitive searches	Collection of regulations and trends at other companies	Draft proposals for various applications and GxP documents, and proposals for modifications

Under these circumstances, we have taken three frameworks. At the top of the list, we will promote the work by using large-scale language models, such as ChatGPT, or other services that will be released soon, which may be quite useful.

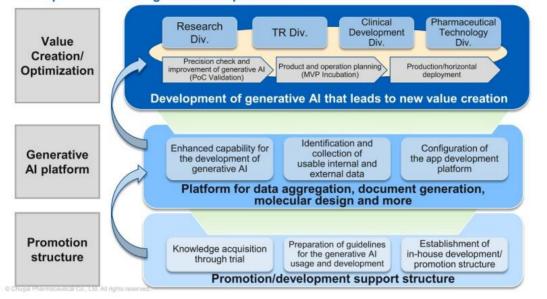
In the middle, we understand that there are some things that will not work well as a solution unless they inevitably make use of in-house data. Typically, there is preparation for standard procedures, company regulations, and other documents, as well as understanding of systems. We would like to create a situation where users can prepare such things easier and more efficiently by reading the data. We would like to realize this environment by making the Digital Transformation Unit burst in these areas as a company-wide lateral function.

At the bottom, as Mr. Ohara explained earlier, the Digital Transformation Unit will support the entire Company by creating the foundations for the IT infrastructure to be used across the entire Company, such as for cross-company searches, or for the infrastructure to be used company-wide, such as for regulations in the industry and trends in other industries. We would like to utilize them to improve efficiency or create new value.

Organizing the Generative Al Development Structure



 Promote the development of generative AI to expedite R&D upon organizing a well-structured developer team and the generative Al platform





For generative AI, including ChatGPT, we will build the promotion structure at the bottom. The middle one is the generative AI platform.

In fact, we recognize that the promotion system will not run well within the Company unless we establish a structure to accumulate knowledge through trials, create guidelines and other mechanisms, and establish a system to promote the system within the Company.

Therefore, after completion of this promotion structure, we would like to prepare language models and other generative AI models, places to consolidate data, and a system to select models, that the business departments at the top will be able to utilize them to create new value. We are now moving forward based on this three-tiered structure.



Our Focus in the Generative Al



- Organize the needs of each unit from the perspective of the technical area that leads to competitive advantage and time to produce results
- (1) "Identification of insights and support for decision-making," (2) "Mining and utilization of latent



While we are working on many things, we are creating priorities within the Company based on an understanding of where a solution fits in the scope by the four quadrants. We organized these four quadrants by taking the consistency between Chugai's strategies and assets on the horizontal axis and the time until the solution can be given on the vertical axis.

"Quickly streamline operations" on the bottom left is the part that covers the entire Company and the area where the use cases that we have already shown are progressing rapidly. In that area, we can categorize operations into parts that can simply be made more efficient.

I think the right side is important, and we would like to implement #1, identification of insights to be generated by players in our core business of research and early-stage clinical trials, and support for decision-making, as soon as possible.

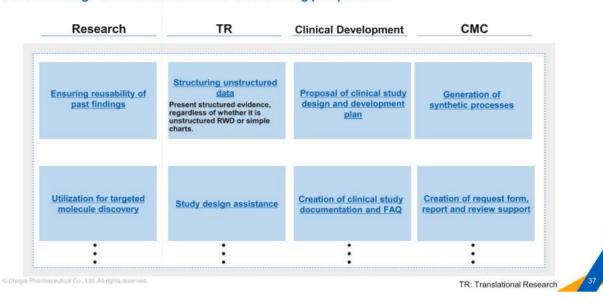
However, it is difficult to take it to that level in a single step, so we are now thinking about #2, "Mining and utilization of latent knowledge within the company," where we can first utilize in-house knowledge, and create new value by using data that has been left unused up to now.



Direction of our Action to Extract Insights and Support Decisionmaking in R&D



♦ We encourage utilization in R&D from the following perspectives:



As we focused on these research and early clinical stages, we have discovered that there are quite a few buried findings in the field of research that researchers have thought a lot about and put into action. We have a strong desire to reuse these findings and will realize this part.

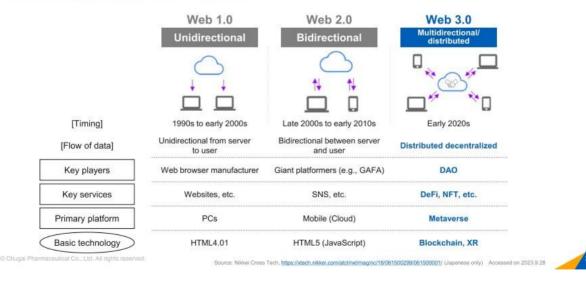
We are also thinking that these values can be brought to the point where they lead to new values, including study design of translational research and clinical development, and we are promoting these initiatives within the Company.



Changes in the Web



 Web 3.0 is a new concept of the Internet since 2020. The key point is that data is distributed and managed by each system/individual, and that individuals directly connect with each other without relying on gigantic IT companies



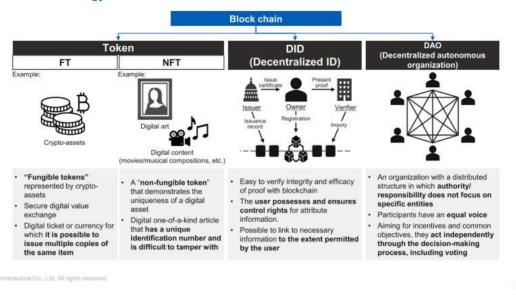
I would also like to explain our next initiative, Healthcare x Web 3.0.

As many of you already know, talking about the transition of the Web, first of all, there was the Web 1.0 era, when the Internet came out. Then came Web 2.0, where two-way interactions, represented by social networking services, began. And I understand that the underlying technology for Web 3.0 is blockchain. The key point is that data is distributed and managed by each system/individual, and that individuals directly connect with each other without relying on gigantic IT companies.

Key Elements of Web 3.0 - Blockchain-related elements (FT, NFT/DID/DAO)



◆ The main elements of Web 3.0, such as "DAO," "DID," and "NFT/FT," are based on blockchain technology



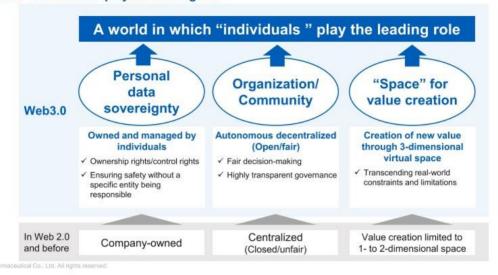
In the context of Web 3.0, the typical blockchain technology is used for issuing tokens, managing decentralized IDs, or, as I will show later in a case study, for autonomous decentralized organizations called DAOs. We believe that the blockchain technology is being used in these cases.



What is Web 3.0? (Chugai's Interpretation)



 Web 3.0 will change ideas about the ideal states of "personal data sovereignty," "organization/community," and "space' for value creation," and realize a world in which "individuals" play the leading role





We see Web 3.0 as a fairly innovative technology and summarize Chugai's interpretation of it.

First, I understand that the data that was held by companies in the Web 2.0 era is owned by individuals in the Web 3.0 era. As individuals hold data sovereignty, a world in which individuals can play a leading role is about to be achieved by such digital technology.

In addition, we believe that the centralized structure will be replaced by autonomous decentralized organizations, so the way organizations and communities exist will change.

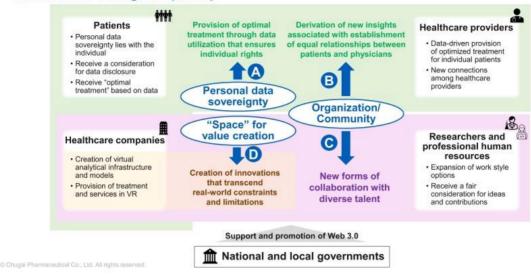
Based on these changing organizational forms, we believe that there will be value creation in the new structure. We now believe that at the center will be a world where individuals take the lead.



Healthcare Worldview Created by Web 3.0



 Through Web 3.0, a world in which each stakeholder in the healthcare field will receive benefits is realized, and the values to be provided in that world can be broadly classified into 4 categories (A to D).





If we project this into the healthcare worldview, among the four main players, patients, medical professionals, healthcare companies, and researchers including academia, we think that we are entering an era in which patients will naturally be able to control who they disclose their data to and how the data is used.

In exchange for providing the information, patients will be able to receive optimal medical treatment and optimal solutions from healthcare companies. We believe that such a worldview can be created.

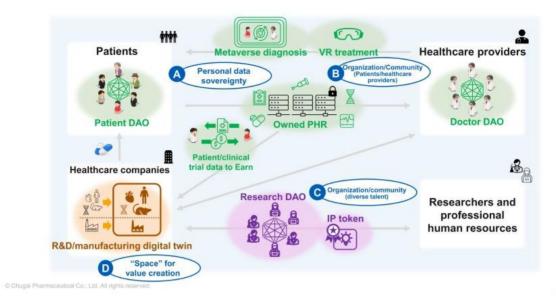
In addition, as indicated in B and C, we believe that the utilization of seeds and IP that have not been created within the normal framework up to now can be put to good use when medical professionals, researchers, and healthcare companies are organized within this DAO structure.



✓ Web 3.0 × Healthcare Worldview (realization image)



◆ Web 3.0 × Healthcare worldview will be realized through new use cases created by Web 3.0





We present the image in this Web 3.0 in a way that focuses on DAOs.

For example, in a patient-driven DAO, an autonomous and decentralized organization that includes not only patients but also pharmaceutical and healthcare companies, as well as professors from academia, we believe that each patient has the right to play a leading role and assert his or her ideas, as the organization includes players who use data provided by patients and those who provide funding.

I believe this will lead not only to DAOs of patients, but also to those of doctors and other researchers.

Example of Realization Image: Research DAO



 Accelerate innovation creation through formation of DAO mainly from collaboration/idea emergence and fair distribution toward the NFT-ization of IPs and contributions



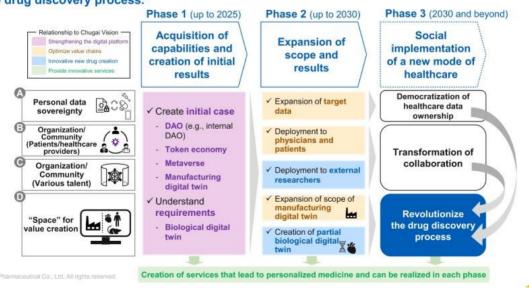
In this context, we present a research DAO as an example of realization image.

Ultimately, we would like to utilize this type of organization in our core business of drug discovery. Therefore, we would like to explore the possibilities of a new mechanism for competition, which will be born from the accurate protection of intellectual property and fair management, a mechanism to create together, and a mechanism that will create new innovations.

Roadmap for Realizing Chugai's vision



 First, we will strengthen our platform, expand applicable use cases by making the value chain more efficient, and ultimately promote the use of Web 3.0 toward crucial "revolutionization of the drug discovery process.



However, we understand that we are not yet in a situation where we can realize such a worldview in a single leap.

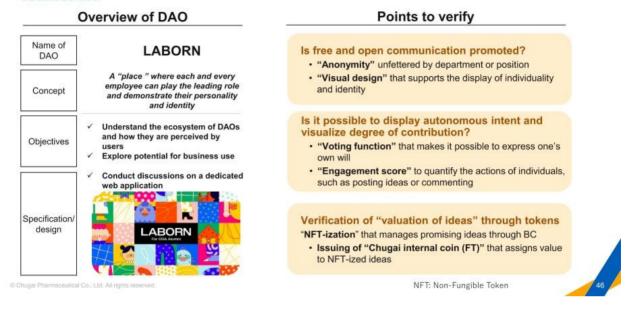
As we set Phase I, I think we are now in the phase of first acquiring capabilities and then understanding how DAO and Web 3.0 technologies can be used in the initial stage. Beyond that, we would like to expand the scope of application and create a worldview where new value is created.



Construction and Operation of Internal DAO



 Construct internal DAO to promote understanding of DAOs and examine the possibility of business use



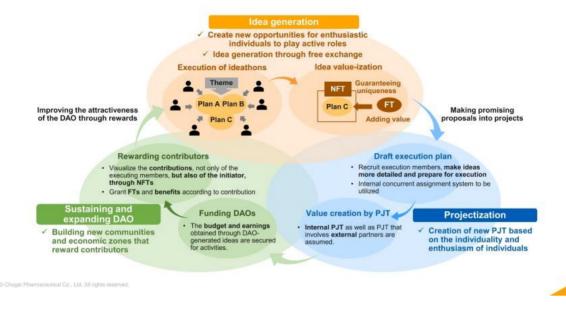
We have just presented a DAO involving outside parties, but in fact, we are now in the phase of working within the Company to see if this autonomous decentralized organization using the Web 3.0 technology, i.e. the blockchain technology, will create new value.

As the in-house name within the Company, we have named it LABORN with the hope that new things will be created in the laboratory. We are now examining whether free and vigorous communication can be generated in such an autonomous decentralized organization, and whether decisions and expressions of intent are reflected in the level of contribution, and how this DAO system can be utilized within the Company through engagement scores and giving the members the voting rights, etc.

Concept of Deployment of Internal DAO



◆ Aim to dynamize new value creation by making ideas spawned by DAO into projects

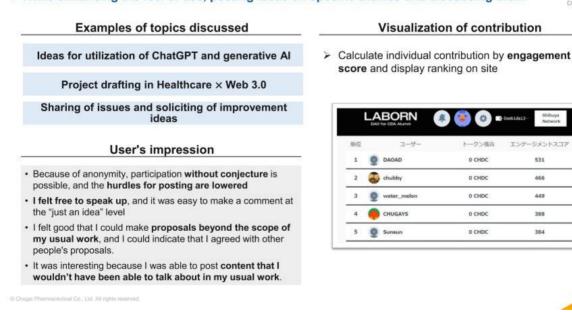


In this DAO, we will generate ideas without being restricted by layers or positions, and when they become projects and produce results, incentives are given to those who first generated the ideas. We would like to verify the value of this DAO by repeating this process.

Overview of LABORN Activities and Feel of Use



While enhancing the feel of use, posting ideas on specific themes and discussing them



We have also compiled a document on the feel of the system, which I would like you to see later if you are interested.

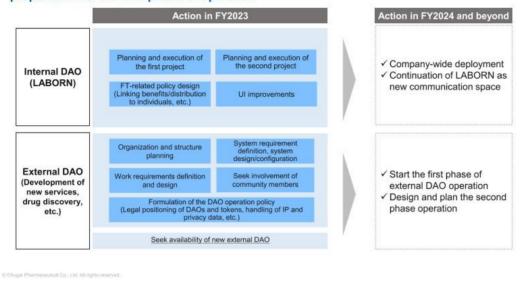
We have received favorable responses within the Company for the anonymity, the desire to be active without being restricted by positions, and the worldview in which individuals can play the leading role.

Support





- For the internal DAO, define and promote projects initiated by DAO
- For the external DAO, proceed with the work/system requirement design and configuration in preparation for the first phase of operation



Finally, we would like to promote the study of internal DAOs that I mentioned earlier, and we would also like to work actively with external players on activities that utilize new technologies, such as this new Web 3.0. I ask for your cooperation and support regarding the opportunities we will provide later.

That is all from me. Thank you for listening.

Miyata: Thank you very much. Next, Dr. Ishii will give an update on the progress of the insight business.

Dr. Ishii, please go ahead.

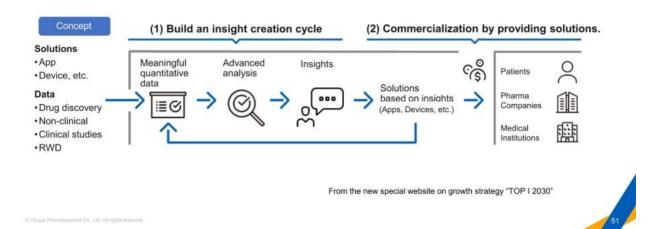
Ishii: Hello, everyone. My name is Nobuya Ishii, Head of Chugai' Science & Technology Intelligence Department.

In the last part of this presentation, I would like to talk about the insight business initiatives.

Insight Business



 Business aiming to provide sustainable medical solutions to improve the value of providing drugs, etc. to patients and other stakeholders



Since this is the first time we are introducing the insight business initiatives, let me start by telling you what the insight business is.

The word "insight" here is derived from "to look inside," which directly translates to insight, intuition, or discovery. Here we are referring to finding the essence from superficial phenomena, or the essence itself.

As shown here, our insight business is aimed at finding insights from data obtained through various channels, developing and providing them in the form of solutions.

The business is comprised of two parts: The first part is to build an insight creation cycle in which provided data are used for the creation of new insights and the second part is to provide solutions based on the insights to various stakeholders and commercialize them.

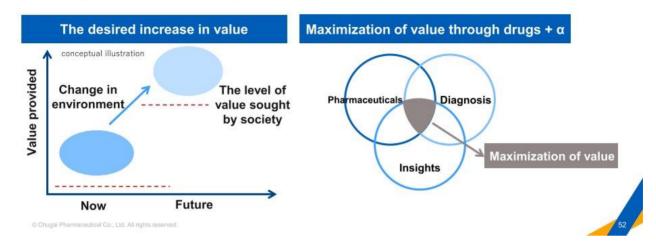
This is intended to further enhance the value of providing drugs and other products, and to realize the insight business, which aims to enable the sustainable provision of insight-based solutions.



Why Take On the Insight Business?



The core business of Chugai is to provide innovative pharmaceuticals, and that remains unchanged. However, as a response to an era in which we are being called upon to provide value that goes beyond the "creation of innovative drugs," we are working on improving the value proposition by providing solutions that utilize insights obtained from the analysis of various data.



Why do we take on the insight business? Chugai's core business remains the same, i.e. the provision of innovative pharmaceutical products. However, we recognize that due to changes in the social environment and technological advancements, society is now demanding that we provide value beyond the creation of innovative drugs.

In response to these changes, there is the need to maximize patient value by combining drugs and diagnostics with solutions that utilize insights gained from the analysis of diverse data.

Furthermore, we believe that in order for this solution to grow sustainably, it is necessary for us to work based on the premise of commercialization. As a response to these issues, we are working to examine the insight business.

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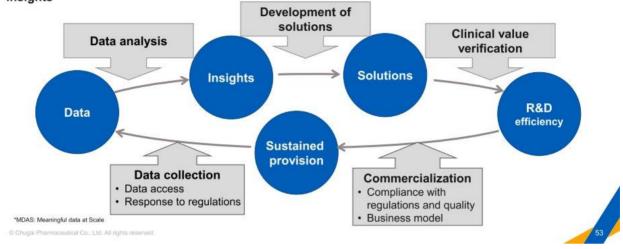
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Insight Business Value Cycle Model



Develop insights obtained from in various businesses such as pharmaceutical R&D activities into solutions to reaprocesseslize a value cycle that leads to (1) maximization of pharmaceutical value, (2) simultaneous generating MDAS* through continuous data acquisition, and (3) creation of new insights



In addition to the commercialization aspect, an important aspect of the insight business is the value cycle model of the business.

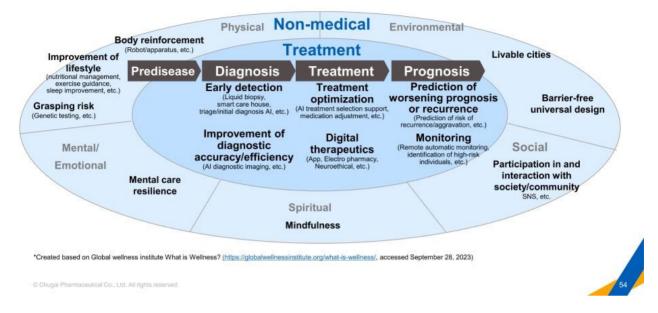
As shown here, the starting point for an insight is data. We find an insight through sophisticated analysis of data obtained through various routes.

To make this insight deliverable, we need to develop solutions. Once the clinical value of these solutions is validated, we expect that these solutions can be used to improve the efficiency of clinical development and also provide value to patients in real-world practice setting.

In order to commercialize these solutions for business provision, we will also need to address regulatory and quality requirements and to build a business model. By providing solutions in a sustainable and widespread manner, new data can be accessed, collected, and there will be a cycle for generating new insights. We will strive to realize the value cycle through the insight business.

Expected Areas where Insight Business to be Rolled Out





The expected areas where the insight business will be rolled out are wide-ranging, from the medical treatment area shown here to the non-medical area targeting healthy people, due to the nature of the insight business solutions as digital solutions.

However, as I mentioned at the beginning, since the purpose of the insight business is to increase patient value associated with the provision of drugs, we assume that the scope of the current insight business is in the area of medical treatment.

Specifically, as shown in the middle, the scope of the business would include early detection, improvement of diagnostic accuracy/efficiency, treatment optimization, monitoring, and prediction of worsening prognosis and recurrence.



Scope of Efforts in the Insight Business

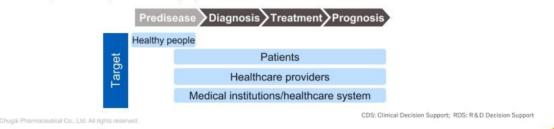


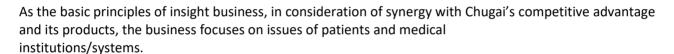
Basic principles

- Focus on patients and pain in medical institutions/systems, considering Chugai's competitive advantage and synergy with the pharmaceutical business
- · Deployment of solutions from Roche in Japan
- Development of solutions related to products created by Chugai, utilization in clinical development, and post-launch deployment

Direction of approach

- · Decision support
 - · Clinical (healthcare providers, patients): CDS
 - · R&D (for companies, including Chugai): RDS
- · Remote Patient Monitoring (RPM)
 - · Clinical (healthcare providers, patients)
 - · R&D (for companies, including Chugai)





The major activities will be the domestic development of solutions to be introduced from Roche, the development of solutions for in-house products, and utilization in clinical development and post-launch.

The two main directions of approach are decision support and remote patient monitoring (RPM). They consist of those used in each R&D situation and those used in businesses.

As shown in the bottom part of the slide, we expect that the solutions will be provided to a wide range of customers, from patients to healthcare professionals and medical institutions, depending on each solution.

Efforts toward Integrated Solutions at Roche



What is an integrated solution?

- Generic term for a non-product-dependent solution that leads to improvement of the value delivered to patients through a patient journey
 - · Early + accurate detection
 - · Timely diagnosis
 - · Remote disease monitoring
 - · Individually tailored care/interventions



Examples of efforts

- Remote monitoring of patients with multiple sclerosis (MS) via smartphone app
- Remote monitoring of patients with ophthalmologic diseases via smartphone app
- Remote monitoring of cancer patients via smartphone app
- Support for analysis of radiological images and pathological images of cancer patients



Javier Garcia Palacios, Global Head of Personalized Healthcare Integrated Solutions in Roche @ VIVE 2023

An activity within Roche group similar to Chugai's insight business is Integrated Solutions.

Integrated solutions are generic term for non-product-dependent solutions that lead to improvement of the value delivered to patients through a patient journey. For example, as shown here, the targets include early and accurate detection, timely diagnosis, remote disease monitoring, and individually tailored care/interventions.

Specific examples, as shown on the right could include remote monitoring of patients with multiple sclerosis (MS), those with ophthalmologic diseases, and cancer patients via a smartphone app. Furthermore, there is AI-based analysis support for radiological and pathological images of cancer patients. It has already been reported that some of these initiatives will be commercialized by the end of the year.



Efforts in the Insight Business at Chugai



TOP I 2030: One of the growth foundation reforms

· With the goal of establishing a business system for the insight business by 2030, we will work on verifying technologies and effects through individual use cases, reexamine our internal system, and establish a model for collaboration with external parties.

	Up to 2023	Verification phase 2024 to 2026	Commercialization phase 2027 to 2030
Activity goals for the insight business	Technology verification through individual use cases	Verification of effects and expansion of scale by application to multiple projects	Establishment of a business structure that will enable continuous creation and sustained delivery of insights
Contribution to charmaceutical business	Maximization of insight utilizati Acceleration of drug R&D with Maximization of product value		nsight business-related activiti

Examples of efforts

	Decision-making support	Remote monitoring
Endometriosis	Diagnostic imaging	•Pain
Cancer	Foundation medicine business Prognosis prediction Early diagnosis	Adverse events/ prognosis
Hemophilia		Asymptomatic hemorrhage Motor function
Eye diseases		• Eye function

The insight business is positioned as one of the growth foundation reforms in TOP I 2030, Chugai's growth strategy.

With the goal of establishing a business system for the insight business in 2030, we will work on verifying technologies and effects through individual use cases,

reexamine our internal system, and establish a model for collaboration with external parties.

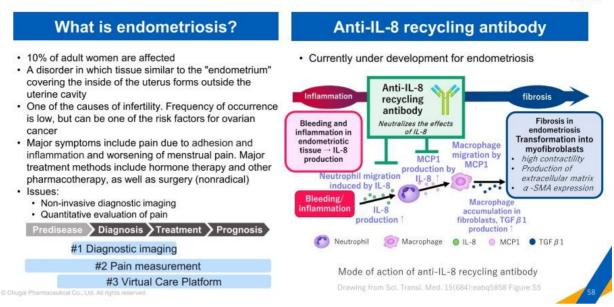
This period up to 2030 is divided into three phases: the exploration phase, the verification phase, and the commercialization phase. Our goals are to verify the technology through individual use cases, to expand use cases and verify their effectiveness through deployment in multiple projects, and to establish a business structure that will enable the continuous creation of the insight business and the provision of sustainable value.

Specific examples of our efforts are still under consideration, and I cannot give too many details, but as shown on the right, we are working on decision support and remote monitoring in disease areas that are in line with Chugai's pipeline.



Example of Efforts in the Insight Business: Endometriosis





Among them, today I would like to briefly introduce a few examples of the insight business initiatives in endometriosis.

Endometriosis, which affects 10% of adult women, is a disorder in which tissue similar to the "endometrium" covering the inside of the uterus forms and outside the uterine cavity. It is one of the causes of infertility and is also known as one of the risk factors for ovarian cancer, though the frequency of occurrence is low.

Major symptoms include pain due to adhesion and inflammation and worsening of menstrual pain. Major treatment methods include hormone therapy and other pharmacotherapy, as well as surgery. Challenges in the disease include the need for noninvasive diagnostic imaging and the difficulty in objectively and quantitatively evaluating pain.

Chugai is currently developing an anti-IL-8 recycling antibody for the treatment of endometriosis, and hopes that the insight business initiative will lead to increased value delivery of this drug to patients in the future.

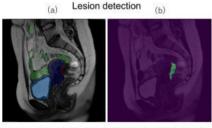


Efforts in the Insight Business, Case #1



Issues in imaging diagnosis of endometriosis

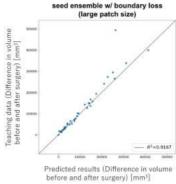
- Current diagnosis: Definitive diagnosis by endoscopy, which is highly invasive, is required.
 Diagnostic imaging is difficult to adjudicate, and evaluation differs greatly among evaluators.
- Variability in efficacy assessment in clinical studies



(a) Segmentation results of lesions (reddish brown), uterus (blue), bladder (light blue),

Efforts

 Efforts to develop models for detecting pelvic organ and nodal lesions by artificial intelligence (collaboration with Preferred Networks)



Results of a prespecified exploratory analysis of a clinical trial targeting endometriosis patients

Provided by Preferred Networks

Case one of the efforts in the insight business is the development of AI algorithms for imaging diagnosis of endometriosis. Currently, the diagnosis of endometriosis requires a definitive diagnosis by highly invasive endoscopy, while it is difficult to diagnose the disease by MRI and other imaging techniques and there are large gaps among evaluators' opinions.

This leads to variability in the determination of clinical efficacy in drug development, and also makes it difficult to accurately diagnose endometriosis and assess its progression.

In collaboration with Preferred Networks, Inc., an AI company, we are developing models for detecting pelvic organ and nodal lesions by artificial intelligence.

As shown on the left, we have succeeded in automatically detecting the areas of probable endometriosis lesions from MR images. Moreover, as shown on the right-side graph, we have created a program that predicts lesion changes in uterine cysts before and after surgery, calculated from annotations by specialists. In the graph on the right, the vertical axis shows the evaluation results by specialists and the horizontal axis shows the prediction results by the algorithm.



Efforts in the Insight Business, Case #2



Issues in pain measurement	E	fforts
Large variation in subjective evaluationVariability in efficacy assessment in clinical studies	 Development of continuous pain measurement technology using digital devices (collaboration with Biofourmis) 	
(1) Visual analog scale (VAS)	- Mechanism of pain in e	endometriosis: autonomic nerves
No pain Use 10 cm scale The worst pain imaginable 100	 Vitals related to autonomic nerve pain: heart rate fluctuation, skin conductance 	
(2) Numeric rating scale (NRS) 0 1 2 3 4 5 6 7 8 9 10 No pain The worst pain imaginable	Objective Pain Measurement Using a Wearable Biosensor and a Mobile Platform in Patients With Endometriosis ClinicalTrials.gov Identifier: NCT04318275	
(3) Face rating scale (FRS)	Wearable Biosensor	Mobile Platform
A B C D E F Chronic Pain Information Center https://itami-net.or.jp/download (Access: September 26, 2023)	Empatica's E4	Biofourmis's Biovitals™ Platform Pain Algorithm Biovitals® Pain Index Mobile app Femme Rhythm™ App
d by Chugal Pharmaceutical with reference to and citation of pain education content data for al education. nugai Pharmaceutical Co., Ltd. All rights reserved.	The E4 wristbund https://www.empatica.com/research/e4/ (Access: September 27, 2023)	

Case two of the efforts in the insight business is the objective measurement of pain from endometriosis. Pain is one of the most difficult symptoms of endometriosis, yet its assessment is subjective, using VAS, or the visual analog scale, and NRS, or the numerical rating scale. These are often pointed out as a problem for judging efficacy in clinical trials, because of the large individual differences.

To address this issue, we are working with Biofourmis, a US company, to try to develop a technology for continuous quantification and measurement of pain using digital devices.

Since it has been reported that endometriosis pain is mediated by the autonomic nervous system, we aim to create an objective pain score by continuously measuring vital signals related to pain by the autonomic nervous system, such as heart rate variability and skin conductance, with a wearable device.

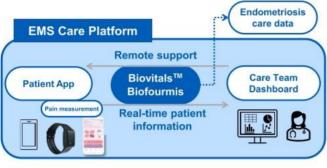
The validation of pain measurement in endometriosis patients using the developed algorithm is currently underway, and the results have already been reported at medical conferences. We look forward to its use in the future for evaluating drug efficacy, monitoring patient conditions, and as a solution.

Efforts in the Insight Business, Case #3



Issues in the delivery of solutions

 Need to build access infrastructure to deliver solutions to patients and medical institutions



Published at 10th Annual Mobilia Tech in Clinical Trials https://hocanferenceforum.org/conferences/mobilis-in-clinical-trials/2023-agenda/ (Access: September 26, 2023) "Scaling Mobile Technologies and Digital Sionarkers to Personalize Therana Development"

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Efforts

- Efforts to deliver solutions through the virtual care platform that Biofourmis provides to medical institutions
 - Development of a virtual care platform that enables real-world pain measurement
 - Small-scale provision of virtual care for patients with endometriosis in the U.S.
 - Find insights from data gathered from platform to support Chugai R&D on endometriosis and post-launch activities for the endometriosis drug candidate under development



Case three is an effort to solve problems in order to provide solutions to patients and medical institutions.

We are working on delivering solutions through the virtual care platform that Biofourmis provides to medical institutions. Using this platform, the so-called remote medical care platform, we are trying to quantify pain from endometriosis.

We are currently developing a virtual care platform for endometriosis patients and are in the process of preparing to offer it on a small scale in the US. Through this platform, Chugai expects to find new insights from collected data, which will support Chugai's research and development activities related to endometriosis and the launch of endometriosis drug candidates under development.

Today, we have introduced the three examples from the insight business related to endometriosis, but there are several other ongoing initiatives and we plan to expand them further in the future.





- Regulatory compliance (medical device regulations, personal information protection, etc.)
 - Acquire capabilities to appropriately protect personal information and comply with various regulations depending on where the solution is deployed (Japan, overseas)
- Involvement of relevant stakeholders (patients, healthcare professionals/medical institutions, etc.)
 - From the solution development stage, we consider the benefits to various stakeholders and build solutions that can provide services sustainably.
- Knowledge accumulation
 - Improve efficiency by accumulating knowledge through creating solution development examples.

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The following table shows the issues that need to be addressed in the future. Regulations for medical devices and regulations for the protection of personal information will become necessary in the future, and we need to acquire capabilities to appropriately protect personal information and comply with various regulations depending on where the solution is deployed, such as Japan and overseas.

In order to promote these initiatives, it will also be necessary to involve relevant stakeholders such as patients, medical professionals, medical institutions, and regulatory authorities. In particular, it will be necessary to consider the benefits to various stakeholders from the early stages of solution development and to build solutions that can provide services in a sustainable manner.

We also believe that accumulating more and more knowledge gained through the creation of solution development cases within Chugai is also necessary to improve efficiency in the future.





- Aiming to commercialize an insight business that realizes the provision of sustainable solutions based on insights to further improve the value provided by pharmaceuticals.
- By developing solutions from insights obtained from pharmaceutical R&D activities and other business processes, we aim to realize a value cycle that leads to (1) maximization of pharmaceutical value, (2) simultaneous construction of MDAS* through continuous data acquisition, and (3) creation of new insights

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Here is a summary. We at Chugai are aiming to commercialize an insight business that realizes the provision of sustainable solutions based on insights to further improve the value provided by drugs.

By developing solutions from insights obtained from pharmaceutical R&D activities and other business processes, we aim to realize a value cycle that leads to maximization of pharmaceutical value, simultaneous construction of MDAS, a meaningful data at scale, through continuous data acquisition, and creation of new insights.

Thank you very much for listening.

Question & Answer

Miyata [M]: We will now move on to the question-and-answer session.

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

Atsumi [Q]: My name is Atsumi from Nikkei BP. Thank you for your explanation. I would like to ask two questions about generative AI.

The first point is that you will build the Chugai version of ChatGPT on Microsoft Azure, is this using Microsoft Azure OpenAl Service?

The second question: You mentioned that you would like to utilize generative AI for drug discovery, which is your core business. What do you feel are the biggest issues in using generative AI for drug discovery as you go through the steps? I would like to ask you about these two questions.

Kanatani [A]: Thank you for your questions. I would like to answer.

As for the first question, we are deploying Microsoft Azure OpenAI internally, and we are in a situation to deploy a system in a secure environment within the Company, making sure that information is not leaked outside. In the multi-cloud strategy mentioned earlier, we are also building a separate environment where we can test various types of generative AI, and we would like to promote the use of AI not only in this environment.

As for the second question, I think that the most important thing is to integrate dry and wet, or life science experiments and computer analysis. There is a lot of data out there that can be done dry, but there is inevitably some wet work to verify them. Therefore, I believe that collaboration between dry and wet researchers will be necessary in the future to optimize the combination of these two methods, such as how to improve efficiency and confirm the accuracy in wet.

Atsumi [M]: Thank you very much.

Hashiguchi [Q]: My name is Kazuaki Hashiguchi from Daiwa Securities. Thank you for the presentation.

You gave us a timeline for the future regarding the use of Web 3.0 and the insight business. I got the impression that you have set a pretty aggressive goal. However, if you are to realize this reform on this timeline, I am afraid that the Company will not be able to keep up with your departments' efforts, even if they are excellent, unless you make solid progress in Phase I, as shown on page six of Ms. Shisai's slide. How confident are you in the current level of achievement of this target?

I don't think you gave us this kind of timeline for the use of generative AI. I wonder if you could also comment on the background of this, whether this is still going to take a lot of time, or whether the timeline is unclear given the current situation.

Shisai [A]: Thank you for your questions. Now that we have finished Phase I and are in Phase II, we are really working on various movements. It is a pioneering effort in the industry.

The key to doing so is the mindset of the employees. We often say that we should not be afraid of failure, but on the other hand, in the midst of compliance issues and various regulations such as GMP, GxP, etc., it is important how to nurture the attitude of employees to work on new things. The Chugai Digital Academy and Innovation Lab, which we started in 2020, are the cornerstones for that.

In addition to that, we have been creating the starting point for expanding ideas. For example, in conducting the Innovation Lab, we have asked ourselves if we can do more with generative AI, or if we can use DAOs or other Web 3.0 technologies to talk with patients using the metaverse, etc.

Therefore, we have nurtured a mindset not only for catching with technologies, but also for challenging those issues immediately for three years. I think that the employees have the impression that new hurdles and new challenges have been set. For example, when we solicited for the trial of the ChatGPT, we received far more applications than the planned number of 500 employees. We have succeeded in fostering such an organizational culture.

The roadmap for generative AI is from Mr. Kanatani.

Kanatani [A]: I think your question was about the timeline of generative AI.

We understand that generative AI is only a tool. Rather than creating something with generative AI, I think it is more about how we can apply it to our core business of drug discovery, such as doubling R&D productivity, and launching global in-house products every year. The technology changes from time to time, and our stance is to use generative AI to achieve our goals, so we have not shown our timeline.

Hashiguchi [Q]: Thank you very much.

Second, I would like to ask you what you think about the risks of the new challenges you are taking in the development related to endometriosis in terms of how to obtain clinical trial data. I think clinical trial data are taken, in part, to help regulatory authorities understand the effectiveness of the drug, and in part to help doctors and patients understand how superior this treatment is compared to other treatment options.

From the regulator's point of view, the new method of data collection may raise doubts about the reliability of the data, and it may be difficult for doctors and patients, especially doctors, to understand how superior the data are when they see them in a different way than they are used to seeing them. How are you dealing with these points?

Ishii [A]: Thank you very much for the question.

We believe this is a very important point. In my talk, I think it was the second of the issues in the future. I think it will be necessary to collaborate with stakeholders early on. The indicators we are using now are authoritative and fairly well established, so I understand that the new method will be used in clinical trials after showing from an early stage, with stakeholder involvement, whether they are equivalent to or have an advantage over the conventional ones.

Hashiguchi [M]: Thank you very much.

Sakai [Q]: My name is Sakai from UBS Securities.

First, as for the business models of your Company and Roche, is this initiative solely limited to the domestic market? If this is the case, I think this will be very costly. How are you considering the profitability and the investment in this project? Please tell us about this point.

Ishii [A]: Thank you very much for the question.

First of all, there are certain solutions in relation to Roche's products, as I explained earlier. On the other hand, Chugai is working on similar initiatives for internally developed products. With regard to that, Chugai will continue to take responsibility in doing that.

As for the business feasibility, as I indicated earlier, we are currently verifying the project by dividing it into three phases, and since we are still in the technical verification phase, we will consider the commercialization of the project in the future. We would like to have another opportunity to explain our progress in the future.

Sakai [Q]: Thank you.

Then, I am not sure if this question is appropriate, but I think it has been a long time since people began to talk about the use of so-called real-world data (RWD). When you come to use the data, for example, the data entered into medical records, including electronic medical records, are often not unified, and it is difficult to obtain uniform data, which naturally makes it difficult to properly obtain data such as the patient's past treatment history and drugs administered. I believe this is especially true in Japan.

For such cases, are you considering that the use of digital technology and AI can significantly improve predictability, and that the collection of data and its linkage to drug discovery can be shortened and made more efficient? Do you plan to launch initiatives to shorten and streamline the process leading to drug discovery, and to make it less expensive? How about these points?

Kanatani [A]: Thank you for your question.

We recognize that there are still many issues to be addressed in the area of RWD. However, we are now collaborating with academia, medical professionals, and companies that use external data, and I believe that we have made considerable progress in understanding where the issues lie with regard to data collection, cleansing, and utilization.

For example, we showed the examples of our use of generative AI today, but we are already seeing the introduction of generative AI in large hospitals in the US, although it is exploratory. We expect that language aggregation will be used quite effectively in areas like interviewing patients and summarizing electronic medical records.

In this way, what is missing from the data is the information on side effects and treatment outcomes, in particular, although those exist as textual information. We want such information as a drug manufacturer. That is quite a big problem that we cannot utilize the data well. We are in the process of examining what kind of initiatives are truly necessary, taking into account the fact that these things will be solved by technology.

Sakai [Q]: I don't think this problem can be solved fairly quickly, but roughly from your point of view, how much time do you think it will take, or what do you think the timing will be when you can truly utilize real data?

Kanatani [A]: It's difficult to say exactly when, but this year, for example, we have utilized RWD to expand the coverage of HER2-positive colorectal cancer agent, as Ms. Shisai mentioned earlier.

I also expect a new trend that the Next Generation Medical Infrastructure Act will be amended so that pseudonym-based information can be used starting next year. I believe that this will lead to the use of data that we have been able to use only for our own decision making in research, but that can be used for comparative purposes outside of trials, such as in clinical trials.

We understand that the number of players utilizing this technology is increasing. Although we are not able to give a definite time frame, as a player, we are actively participating in this effort with the expectation that the issues will be resolved as DX for healthcare reform progresses.

Sakai [M]: Thank you very much.

Shisai [A]: As Mr. Kanatani just mentioned, we issued a PoV in 2021 regarding the utilization of RWD and indicated the direction of utilization as a pharmaceutical company, and I think the world is moving gradually with the revision of the Next Generation Medical Infrastructure Act and the certification of pseudonymbased information providers. The unification of electronic medical records is also a major theme, and I think that the current administration or the Ministry of Health, Labour and Welfare and others involved in medical DX have made a lot of progress compared to back then.

We would like to prepare to become an accredited user of the service, in line with the development of the law, after we examine the incoming guidelines next year.

Watanabe [Q]: My name is Watanabe from the Chemical Daily. Thank you for your explanation.

I would like to ask about the insight business. In the last slide of the summary, I think you referred to the data obtained from the activities of each process, each process of R&D, I believe. At this time, in the case of endometriosis, which you showed us as a specific example, what kind of data is being collected through clinical trials, and can you explain how the data can be used in areas like imaging diagnosis, pain measurement, and the likes?

Ishii [A]: Thank you very much for your question.

Since we are still verifying this, we have not yet reached the point where we can collect concrete data through clinical trials. What we said here is that we have only verified whether this solution really achieves this efficacy and performance as expected, using data already obtained in clinical trials.

As to what kind of concrete data can be obtained, I think it depends greatly on the regulations of each country and how far it is accepted in society, as was mentioned in a previous question. We expect that if patients feel that they can benefit from such data, we will be able to get a lot of data.

Watanabe [Q]: I see.

As a specific drug, you are developing an IL-8 recycling antibody. As for the schedule for commercialization in the future, there are the verification phase and the commercialization phase on page 57 of the presentation materials. At the same time as this drug is launched, are you planning to develop the insight business as value added concurrently with the launch of the drug?

Dr. Ishii [A]: Thank you for your question.

The schedule for the development of drugs is not always as smooth as we would like, so we are thinking of developing this solution separately from the drugs, and moving forward as appropriate, while it would be

the best situation if we can synchronize them well. Our plan is to develop this solution in a way that we can demonstrate it in society at the earliest possible time.

Watanabe [Q]: I see. By confirmation, I assume you are referring to AMY109, an antibody in development, and that you will naturally utilize the data from the clinical trials of this drug?

Dr. Ishii [A]: Yes. We consider that the data will be fully utilized as a validation of the solution we are currently developing.

Watanabe [M]: I see. Thank you very much.

Miyata [M]: Ms. Sogi from Alliance Bernstein Japan, please go ahead.

Sogi [Q]: Thank you.

I have a question regarding the insight business. Of course I do not think that this is something that can be done right now. However, I think that it is difficult to commercialize this business in Japan unless it is paid for by medical fees. Do you think about the business in that direction?

At the moment, of course, I think your Company is discussing the issue with the Ministry of Health, Labour and Welfare, though you are still in the early stages. Could you tell us what the Japanese government's vision is for promoting the health of the Japanese people by accepting the application of official medical fees to this insight business?

Dr. Ishii [A]: Thank you very much for your question.

As for the discussions of commercialization of the insight business, the medical regulations, and whether the expenses can be reimbursed by insurance after the product obtains approval as a medical treatment device, the premise is that it cannot distribute proper information to patients unless it is approved as a medical device. Since there is a part that depends on how it is categorized in the regulations for medical devices, we cannot discuss at this time whether we necessarily aim for approval of a medical device or not, and we think it is a case-by-case basis.

As for the reimbursement by insurance,

as I mentioned earlier, at present we are discussing whether or not each solution is equivalent to a medical device, but we have not yet fully discussed what to do beyond that point. I believe it is a necessary matter.

Sogi [Q]: I understand. Thank you very much.

Isn't there any discussion yet on the direction of the Japanese government's regulations or medical fees for this insight business at this point?

Dr. Ishii [A]: No. We are still in a situation where we have not done enough.

Sogi [M]: I understand. Thank you.

Numata [Q]: I am Numata from MIX. I would like to ask about generative AI.

I have two questions. The first one is that you have shown us the use cases for R&D, but I would like to know what kind of use cases you are thinking of for other areas, especially in the sales and marketing area.



Second, in terms of the future use of generative AI, I think you still have a long way to go in terms of how generative AI will be used for business customers, such as medical professionals and patients. What is your outlook for this area?

Kanatani [A]: Thank you for your questions.

The first question was about use cases other than R&D, specifically marketing and sales. As was mentioned earlier at the beginning, in the area of improving sales efficiency or creating insights from customer information, a lot of information is accumulated daily in the activities of MRs (medical representatives), medical information specialists, and MSLs (medical science liaisons) and the information is still left unused.

Therefore, I think that one use case is to find new clinical questions, and through discussions with doctors based on those clinical questions, find new areas of unmet medical needs in the world and link them to such activities.

Regarding the way to utilize generative AI for customers, especially patients, we cannot provide drugs directly to customers yet. If we start providing new solutions directly to customers, as in the insight business, I think there will be considerable use of generative AI, but to be honest, I don't think we are at that stage of discussion yet.

However, I think that one of the challenges is how to deliver accurate information efficiently in terms of daily information and inquiries from patients about drugs and information provided by us. Therefore, we would like to proactively create a system that provides access to appropriate information for inquiries, our own communication, and access by patients.

Numata [Q]: Thank you.

How about medical professionals? I guess you are probably receiving inquiries from medical professionals in terms of utilizing generative AI.

Kanatani [A]: There is a question of how far we can cooperate, but as I mentioned earlier, I believe that information from patients is also important information for medical institutions. As mentioned earlier in the question about RWD, we, as a player on the utilization side, would like to make use of this important data and build a mechanism to compile information from patients as necessary information.

Therefore, we would like to collaborate with medical institutions and patients on what kind of information to collect and how to summarize it into data that can be optimally utilized.

Numata [M]: Thank you very much.

Yamaguchi [Q]: I'm Hidemaru Yamaguchi from Citigroup.

It may be difficult to talk about specific examples, but most recently, I believe your Company has launched Vabysmo since the establishment of the current type of organizational system. I don't know of any specific examples, but I would be interested to know if your Company has taken a slightly different approach to promote the product this time with the inclusion of various digital items.

Shisai [M]: Sorry. I don't understand the purpose of your question, are you questioning the launch of Vabysmo and what?

Yamaguchi [Q]: I would like to know how much of your digital approach and digital marketing approach was used in the launch of Vabysmo.

Shisai [A]: Specifically, we don't have a specific digital strategy for Vabysmo. However, I am sure that the sales division is considering some kind of approach to the use of digital technology in providing information to various key doctors and in the field of ophthalmology, which is a relatively new field for us. However, there was no particular support from us in that regard.

Yamaguchi [Q]: I understand.

One more question briefly: There was a goal of ensuring reusability of past findings in "Direction of our Action to Extract Insights and Support Decision-making in R&D." I think it is very important, but I wonder if it is very difficult to gather past findings. I would like to ask you to introduce one of the ways in which you have been collecting these items.

Kanatani [A]: I would like to answer your question, as I think it came up in the context of generative AI.

As you say, I think one major internal issue is whether it is really possible to create information that can be analyzed. However, I think that all kinds of information can be used in the future, whether it is experiment notes, minutes, online communication in experiments, or chat-based communication, etc.

You don't understand everything about the person who is sitting next to you even though there are official records on the person. The concept I explained earlier is that this technology will allow us to retrieve the necessary information at the necessary time. First, we need to organize the data, create a condition where they can be utilized, then build a model, and so on.

Yamaguchi [M]: Thank you very much.

Miyata [M]: Thank you.

This concludes the Chugai DX meeting.

If you have any questions that we were unable to answer due to time constraints, please contact the Corporate Communication Dept. separately. The phone number and email address are provided on the last page of the presentation materials. We would also like to ask for your cooperation in filling out a survey form, which is available to the participants at the venue. If you are attending via Zoom, the survey form will be displayed when you leave. We ask you to fill it out.

Thank you for joining us today despite your busy schedules.

[END]

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