

Astellas Pharma Inc.

Digital Transformation of Astellas Pharma

January 21, 2022

Event Summary

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Naoki Okamura Chief Strategy Officer and Chief

Financial Officer, Chief Business Officer

Shinya Suda Senior Vice President, Information Systems Ikuno Fujii Head of Corporate Advocacy & Relations

Presentation

Fujii: Thank you for attending the Media Briefing on Digital Transformation of Astellas Pharma. I will serve as the moderator today. I am from the Corporate Advocacy and Relations Department. My name is Fujii.

First, I would like to explain how to answer questions during the Q&A session in the latter half of this presentation. You can ask questions using the question form on the right side of the screen. Questions can be submitted at any time, including during the presentation. Please note that if there are multiple questions with the same purpose or content, we may introduce them together. Thank you in advance for your understanding.

Today's presentation will be made in accordance with the presentation materials posted on our website, so please have them ready at hand.

Let me introduce the participants today: Mr. Naoki Okamura, Chief Strategy Officer and Chief Financial Officer, Chief Business Officer; and Mr. Shinya Suda, Senior Vice President of Information Systems.

Forward-looking statements, such as business forecasts and development prospects in materials, verbal explanations, and Q&A sessions today, are based on the judgment of the Company using the information currently available and include known and unknown risks and uncertainties. Please note that actual results may differ materially from these forward-looking statements due to various factors.

This presentation contains information on pharmaceutical products, including those under development, which is not intended to constitute an advertisement or medical advice. This presentation is also available in English through an interpreter, but we cannot guarantee its accuracy.

Mr. Okamura, please.

Okamura: Thank you very much. Once again, I am Okamura. Thank you very much for today. Today, I will talk about the management policy, management plan. And then, Mr. Suda from Information Systems will share with you some concrete examples and initiatives.

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Let me start using the slide, "Reasons to engage in digital transformation."

Vision

Vision

On the Forefront of Healthcare Change to Turn Innovative Science into

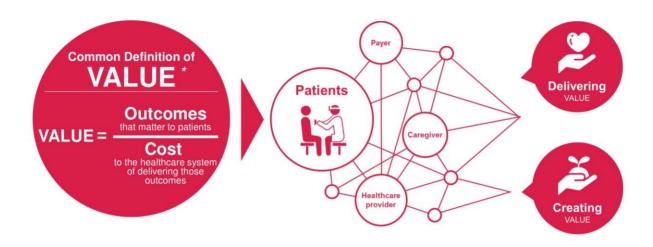
VALUE for Patients

We will achieve sustainable growth by pursuing innovative science to produce medical solutions that provide VALUE to patients



As mentioned, and shown in the video, let us reconfirm our vision: "On the forefront of healthcare change to turn innovative science into VALUE for patients." Based on this vision, we are running our company.

Definition of VALUE

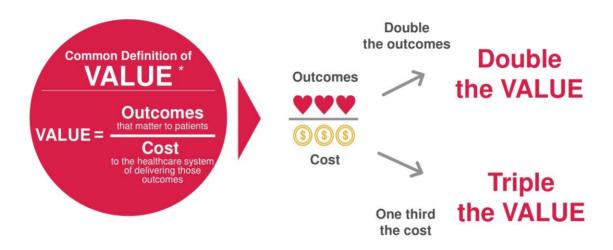




*Adapted from "What Is Value in Health Care?" Porter, M.E. (2010). New England Journal of Medicine

First of all, what is this VALUE? We thought we needed to define this VALUE first and foremost. Professor Michael Porter, of Harvard Business School, was quoted here: "Value is the outcome that really matters to the patients." That is the numerator. And the cost to the healthcare system, as a whole, not just Astellas, but the entire healthcare system of delivering these outcomes, this is the denominator. Our job mission is creating this VALUE and delivering this VALUE to our patients. This is what we are dedicated to.

Definition of VALUE



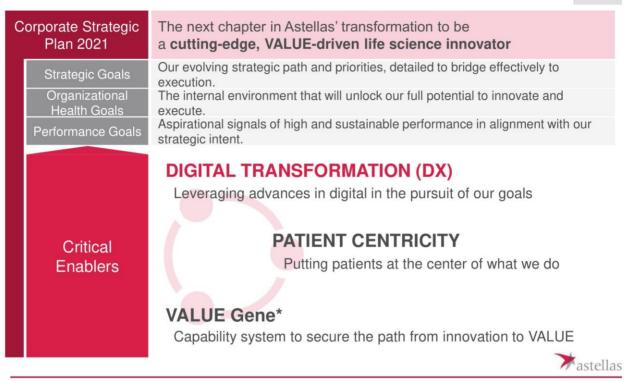


*Adapted from "What Is Value in Health Care?" Porter, M.E. (2010). New England Journal of Medicine

Now let me be more specific on this value.

One example. We develop pharmaceutical products, and the responder rate of the patient, let's say, the responder rate is 30% with a particular product, now. if we can double the responder rate to 60%, the outcome will be double. So, the VALUE becomes double.

A pharmaceutical company tends to focus more on improving the outcome. But in reality, based on the definition of VALUE, even with the responder rate at 30%, if we can identify the patients correctly, then the outcome can remain unchanged and reduce the cost to one-third, which means the VALUE will triple. Pharmaceutical companies focus not just on the outcome in improving the outcome, but also reducing the cost; we have to focus on both.



^{*} VALUE Gene: A set of five capabilities that Astellas has uniquely identified

In May of last year, we announced the corporate strategic plan, CSP2021. The creation and delivery of VALUE, three strategic goals. And to ensure the achievement of strategic goals, we set up three organizational health goals, and the direction that we need to aim for in five years' time, like the North Star, the performance goals that are further down the road were set and established. We've been explaining this since last year.

Internally, these three goals will be achieved through various measures. One of those is digital transformation.

So here, it's saying critical enablers. First of all, patients are the center of whatever we do. So patient centricity. I have the Patient Centricity department under me. Secondly, the VALUE Gene. The cutting-edge, VALUE-driven, life science innovator is our goal.

So how we differentiate ourselves from the others, and how we can efficiently and effectively create and deliver VALUE. When we think of that, we have five organizational capabilities that we identified. We want to elevate that all to the global level and combine this capability flexibly to become a unique one-of-a-kind pharmaceutical company.

astellas

Ideal state of management	Data-driven management		
DX roles	Provide innovative technologies, AI, robotics, and platforms that will revolutionize the way solutions are designed, created, tested, and analyzed		
DX effects	Creating New VALUE	Increased Productivity	Preparing for Risk

Third is digital transformation. We will utilize the advancement of digital to pursue our goals.

Needless to say, the reason to engage in digital transformation is that we provide innovative technologies, Al, robotics, and platforms that will revolutionize the way solutions are designed, created, tested, and analyzed. In using that, we will create new value. As we create and deliver VALUE, we will increase our productivity and also prepare for risks, including cyber risk security, which is rising these days.

This is what we want to hone through digital transformation. Including concrete examples, our digital transformation initiatives will be explained by Mr. Suda. Suda-san, please.



Suda: Thank you very much. Good afternoon, ladies and gentlemen. I am Suda from Information Systems.

Personal history

Shinya Suda

Senior Vice President, Information Systems

Brief Personal History

1992 Joined the former Yamanouchi Pharmaceutical (currently Astellas Pharma)

2004 In charge of IT Integration Secretariat of Merger Preparation Committee

2008 IT Division, UK Subsidiary2011 Director, Corporate IT Division

2015 Vice President, Information Systems (Present post) through globalization of Information Systems Division

Awards

2021 Forbes JAPAN CIO Award "Management Contribution

Award"





This is my bio. In 1992, 30 years ago, I joined the former Yamanouchi Pharmaceutical as the researcher. Since 2015, I've been Global Information Systems Division Head.

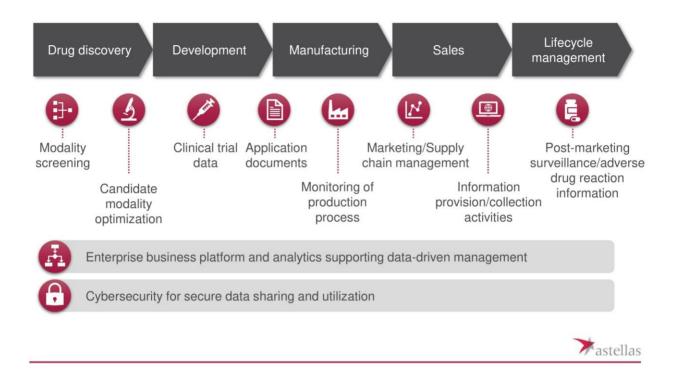
Estimation of "digital technology utilization effects" by consulting firms



^{*}Earnings before interest payments, tax depreciation, and amortization

The development of a new drug is set to cost a lot of money in a long period of time. It costs tens of billions of yen and takes 10 to 20 years. This is the consulting firm's estimate, but the cost may be reduced by 60%, and the duration may be shortened by two to three years. There's a possibility of reduction. In the R&D of drugs, the probability of success is very low. It is set to be 1 in 10,000 to 30,000, so increasing the probability, shortening the duration, and reducing the cost is the role that we think digital transformation can play.

1 - Handling massive amounts of data throughout the value chain

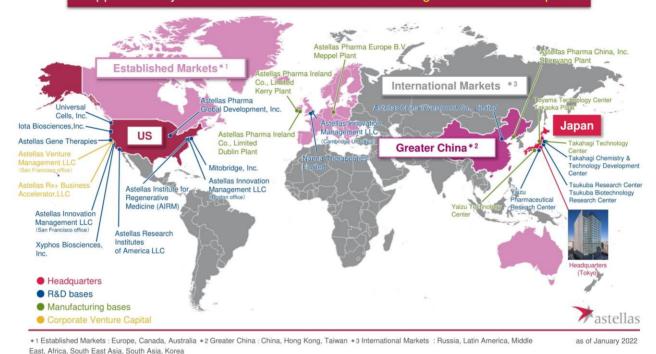


Pharmaceutical companies do drug discovery, development, manufacturing sales, and life cycle management. Through this value chain, we develop, create, and deliver VALUE.

In this entire value chain, we handle a massive amount of information. I will not go into detail, but we utilize this value chain. Beneath it, you can see the back office that supports the value chain, HR, procurement, and finance. In these functions, we use data to realize data-driven management.

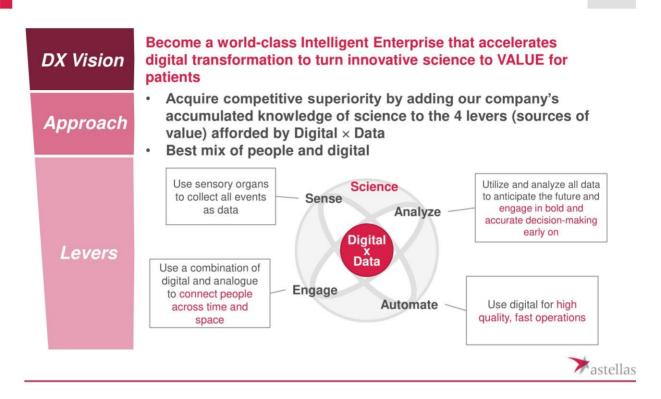
As mentioned earlier, cybersecurity is a focus so that the data we use can be shared and utilized with sense of reassurance. So, this is what we are focusing on now.

- Conducting business in more than 70 countries around the world
 - Approximately 78% of FY20 sales revenue is from regions other than Japan



From a global perspective, Astellas is a global pharmaceutical company and is operating its business in more than 70 countries. R&D, manufacturing, sales. and the headquarters function, have global access spread across the globe, and digital transformation initiatives are basically a global project.

However, digital transformation compared to the traditional system development, it has more unforeseeable uncertainty. So rather than starting this in one goal, we start from one country or one function on a smaller scale, do POC demonstration trial and see the results, and then decide to expand. That is the method we take.

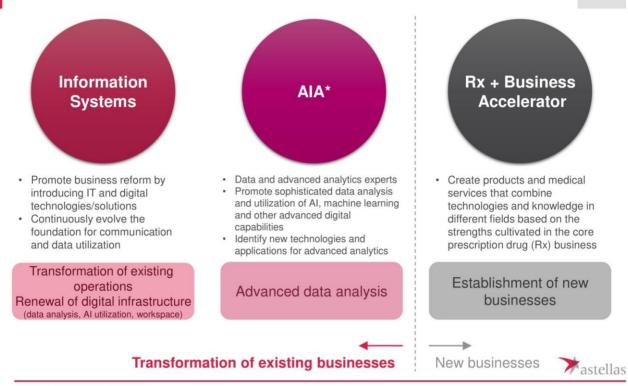


On this slide, we named this digital ambition in 2025. In order to achieve CSP, Astellas will use digital transformation and aim for this DX vision. The method we take is shown here under "approach."

DX vision is "become a world-class intelligent enterprise that accelerates digital transformation to turn innovative science to VALUE for patients".

To achieve this vision, digital acquired the competitive superiority by adding our company's accumulated knowledge of science -- the four levers shown in the bottom half of the page -- and sources VALUE afforded by digital multiplied by data.

Science knowledge that we have cultivated over the years is added on to that to come up with the R&D that is superior to others. All and robotics should not just be used for the sake of the usage. We need to utilize and offer people to exert their capability and be very active. Through the best mix of people in digital, we want to become the best intelligent enterprise.



^{*}Advanced Informatics & Analytics

The main departments that are in charge of digital transformation.

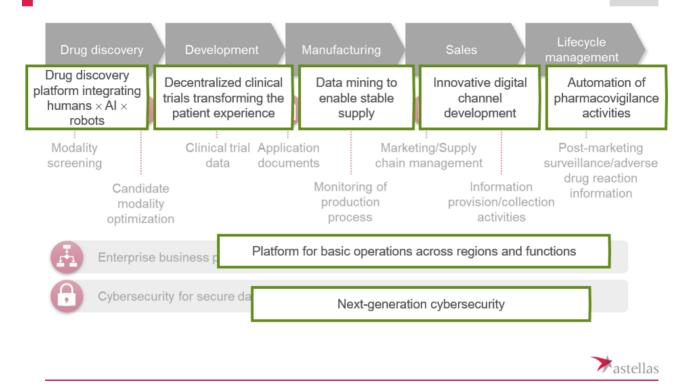
Through the value chain I mentioned, we handle a massive amount of information, and there are multiple systems to do the job. The left two departments are the transformation of existing businesses, and on the right side, our Rx+ Business Accelerator is digital and nondigital technology used to create new businesses.

Today, I will talk about transformation of existing businesses, so I will talk about the two on the left.

First is Information Systems. This is the so-called IT department. IT and digital technology of the existing business is introduced to transform existing businesses, or digital platform is introduced and refreshed.

AIA. This stands for Advanced Informatics and Analytics. This is a data analytics expert panel. Sophisticated data analysis, AI, and machine learning are utilized to conduct the data analysis, and generate knowledge, and utilize in the business.

These two departments are leading the digital transformation of the entire company, in collaboration with other departments.

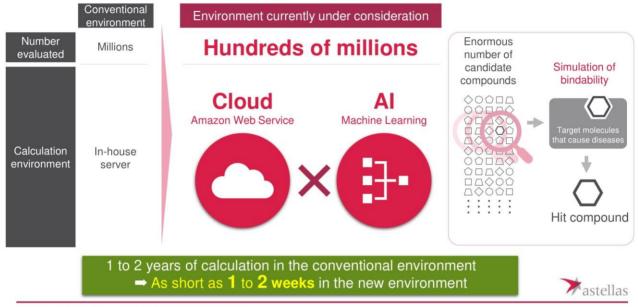


Next, I will talk about digital transformation examples. Through this value chain, in each domain, we have typical representative examples. Let me go one by one. In addition, the back-office initiatives and cybersecurity will also be addressed.

Ultra-large-scale virtual screening



- The more compounds are evaluated, the higher the likelihood of obtaining "compounds that readily bind to targets and exhibit robust pharmacological effects"^{1,2}
- → Forecasting through high-speed, large-volume calculation is a prerequisite for finding good candidate compounds



- 1: https://www.nature.com/articles/s41586-020-2117-z
- 2: https://www.nature.com/articles/s41586-019-0917-9

I forgot to say this earlier, but I may skip some slides. I am on page 19. I'm sorry for that.

There are three initiatives on drug discovery. First is the ultra large virtual screening. On the right side of this page, you can see the gray part, the first stage of the research, the target molecules that cause diseases. We start from finding the compound that binds this. If it fits the keyhole and find the key that can successfully open the door, that's the image.

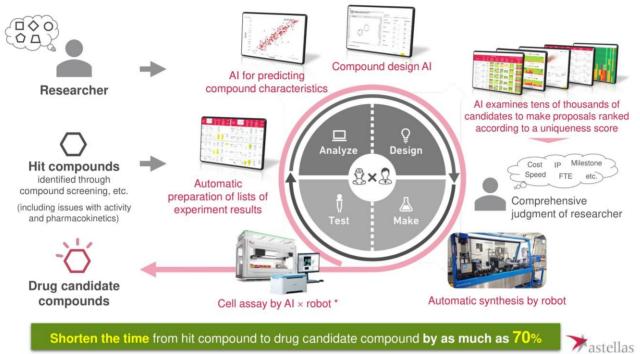
There are an enormous number of candidate compounds. To find the right one, the more the compound to evaluate, the faster we find the one that binds successfully. Traditionally, we had a high-performance server internally. That server was used, and millions of candidate compounds, which we call the library, we evaluated millions of compounds from the library to find the one that has high bind ability.

In the new initiative, we do not use the internal server, but the Cloud, AWS, the infrastructure computer resource and have the machine learning that simulates the bind ability to have hundreds of millions of compounds at one time. Not only the compounds registered in the library, but logically synthesizable compounds that are even not even registered in the library are also evaluated to find the Hit compound that fits the target molecule. It is still under validation. But in the previous environment, it took one or two years for calculation, but it can be reduced to as short as one to two weeks in the new environment.

"Human-in-the-Loop" drug discovery platform integrating humans \times Al \times robots



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^{*}Image source: Beckman Coulter, Inc., Yokogawa Electric Corporation

This is people, AI, human AI, and robots. The Human-in-the-Loop drug discovery platform, integrating humans, AI, and robots. On the previous page, we found the Hit compound that binds the target molecule. So, this is the starting point. But this compound may be soluble to water or its adequacy as the pharmaceutical product is not high. And so, we need to evolve this to a drug, and that is the drug discovery platform.

Using AI, this Hit compound, the similar structure is designed, and these many compounds that are designed are estimated by the AI on the water solubility, and tens of thousands of candidates are examined by AI and scored. The one that has higher suitability as the drug will be synthetically synthesized automatically by robot, and then the cell assay by another robot, the result looked at and evaluated.

So, we repeat the cycle. Using the computer AI and robots, we can do this at a high speed.

So, I mentioned human, AI, and robot. This is Human-in-the-Loop. Just by combining AI and robot, this route can be completed. AI can do high-speed calculation, but the continuous data is estimated. That's AI's strength. But it cannot do this in a discontinuous way with will and intention. That is the researcher's strength, or serendipity, if you will.

So, the researchers, humans, create the discontinued future. That is also another part. So, I put researcher on the upper left hand and the automatic ranking and proposal. In addition to science data, there is information that is not in the form of data, and these are all comprehensively analyzed to come up with the compound that can possibly be promising. Narrowing down, this requires the researcher's judgment.

So, people, humans, and AI, robots, will use their own strength and collaborate with one another to operate this loop. With that, the time from Hit compound to drug candidate compound can be shortened. That is what this platform is doing.

Since we have been operating this, it's been a year compared to the past research results. It took probably two years from the Hit compound to drug candidate compound, but it is reduced to as short as six months. We have this track record now.

World's only "Mahol-A-Ba" cellular drug discovery platform Pesearch on iPS cells requires the "expert skills" of experienced researchers: technique and powers of observation Human resources for iPS cell research are limited, and this is one of the bottlenecks in research Acceleration of research through researcher × AI × robot collaboration Past Current # Samples >10 *1,000 ~ >10,000 "Mahol-A-Ba"

2017.11

Conduct experiments at 100 ~ 1000 times the scale

with precision and reproducibility as good or better than a human expert

Al Machine Learning

Manual

The third area of research is world's only Mahol-A-Ba cellular drug discovery platform.

"Expert arm" robot

Inclusive of the iPS cells, the research on cells requires more expert skills. However, there is only a limited number of researchers who have such expert skills. Also, even experienced researchers have difficulty reproducing the same operation each time. This is where a robot comes in.

As you can see in the picture, there is a robot introduced called Maholo, and it conducts cell culture, as well as the cell manipulation. In addition to using Maholo, as I have said in the earlier slide, we are combining robots with other equipment, as well as the cell assays and expert's arm. Expert's eyes are controlled by AI in the platform. And we created Mahol-A-Ba cellular drug discovery platform with that structure.

People would only be able to do dozens, as well as there will be discrepancy to the results. However, by using Maholo, as well as the platform that we have created, we are able to conduct simultaneously experiment of 2,000 to 10,000 with high reproducibility. We are able to conduct experiments at 100 to 1,000 times the scale. We can do that 24/7.

Support

Experiment

Japan 03.4405.3160 Tollfree 0120.966.744 "Expert eye" robot

Astellas unique system*

^{*}Image source: Beckman Coulter, Inc., Yokogawa Electric Corporation

In addition to this, under COVID-19, it will be difficult for the researchers to go to the research center each day. However, with virtual screening and utilization of robots, researchers would be able to conduct experiments remotely.

This is still at the research stage. But by accumulating the know-how, I think that this would be conducive to delivering the new drugs to our patients. We will be working on this initiative further.

Decentralized Clinical Trials (DCT) Patient-centered remote clinical trials



- In clinical studies for patients with no treatment options, it is essential to "deliver information and gain understanding" and "incorporate the needs of patients into clinical studies."
- → Clinical study transformation based on patient centricity

Image of communication on clinical trials for muscle diseases



From here, I would like to talk about clinical trials, and I would like to introduce the concept of decentralized clinical trials, or virtual clinical trials.

We have defined it as patient-centered remote clinical trials. Clinical trials are an essential process in showing that a pharmaceutical product is effective and safe on humans. However, for patients, there may be some burden for the participation in clinical trials. We want to minimize the burden for the patients so that the clinical trials would become something that is very good for the patients.

We want to conduct clinical trials with patient centricity. We are changing the way that we are conducting clinical trials, and we want to materialize patient centricity. We would like to utilize digital technology in realizing that.

For you to have an image, I would like to show you two images of communication on clinical trials for muscle diseases.

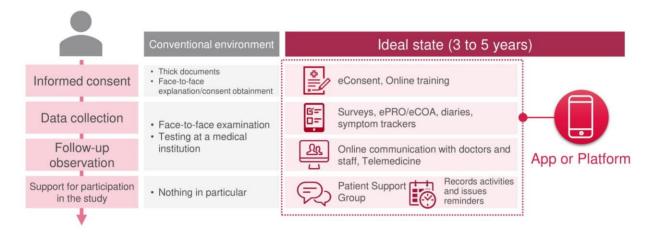
For the healthcare professional, when they are trying to test their abilities for movement, the patients may be thinking that they want to have the evaluation of improvement in their activities of daily living too. Also,

in the case that patient has to go far away medical institutions, it may be difficult for them. They may not be able to bring the medical device that they are using to a plane, even though they have to get on a plane to get to a location of the clinical trial.

What we have tried to do is to conduct a project which enables patients to participate in the clinical trial without going on site.

Decentralized Clinical Trials (DCT) Patient-centered remote clinical trials





We are considering developing and globally deploying a platform that can cover entire process of clinical studies



ePRO: electronic Patient Reported Outcome eCOA: electronic Clinical Outcome Assessment

First, for a clinical a trial, there needs to be informed consent acquired after explanation of the clinical trial, and there will be health checkups and examinations, as well as testing. After that, there would be support provided after the clinical trial starts. When informed consent is obtained, thick documents are used and also the explanation must be face-to-face, and the patients must be on site to listen to those explanations.

As for data collection and follow-up, the patient needs to come to the medical institutions, and data must be collected each time, and there would be face-to-face examination by doctors. This is a burden for patients.

The ideal state is on the right. Informed consent would be obtained online, for example. And for the patients who are staying at home, the candidate drug which is used in the clinical trials could be sent to the patients. At home, it can be input using apps, as well as examination by doctors. It could be done remotely.

Those are the things that we are trying to establish.

The remote clinical trials are being tried out in many forms by various companies. There are apps for e-consent, the data collection app, as well as online examination app, and the applications differ by clinical trial.

These remote clinical trials are being conducted with the aggregation of many small apps. This would still add burden to patients, medical institutions, as well as to pharmaceutical companies. We want to develop something that can be integrated into one platform and roll it out globally for the friendliness to the patients, as well as medical institutions.





Examples of digital use in ASP0367 US clinical trials



Patients with hereditary muscular disease (Duchenne muscular dystrophy) Decreased muscle function, muscle atrophy, decreased endurance in exercise, increased fatigue, etc.





This is an introduction of the example of digital use in ASP0367. This is a clinical trial for patients with hereditary muscle disease. This was done in the United States.

I have been talking about patient centricity. In order for clinical trials to begin, we need to have a certain number of patients. By reducing the burden of the patients, we would be able to increase the number of patients at an earlier stage or to participate in the clinical trial. There may be some dropouts if the burden was too big during the clinical trial.

So, we would like to reduce the number of dropouts as well. By enabling that we would be able to shorten the clinical trial period and also would be able to deliver the new drug earlier than before.

That's what we are targeting.



Our own data mining system for manufacturing: "DAIMON"



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- It is the mission of a pharmaceutical company to maintain a stable supply of drugs to patients.
- · Quality and production issues have a critical impact on patients' health and result in loss of social trust in the company
- → Increase the sophistication of manufacturing in order to continue delivering better quality drugs to patients



Understanding products and production processes

- Huge amounts of manufacturing site data
 Real-time collection and management
 - ✓ Comprehensive analysis and monitoring

Preparedness for dealing with quality and production issues

- · Investigation of the cause of trouble
- Identification of potential risks and detection of changes
- · Risk prediction and prevention



I will be skipping to page 26.

This talks about the usage of data in manufacturing. We have a data mining system for manufacturing called DAIMON.

The pharmaceutical company's mission is to stably provide the drugs to patients in a trustworthy manner. If there are issues about the quality or manufacturing, this may pose a threat to the health and lives of the patients. And also, as a pharmaceutical company, we would be losing our credibility.

So, we need to conduct manufacturing using data so that we can stably provide trustworthy products.

That's DAIMON.

This is a unique technology which utilizes a data mining. In 2013, we started the deliberation, and in 2015, we started development. From 2018, this has been in action.

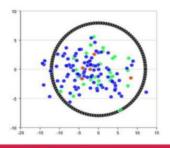
Many companies have been talking about Smart Factory, as well as manufacturing using AI. We are not using AI, but we have been able to do advanced sophisticated data analysis to be used in quality assurance.

Our own data mining system for manufacturing: "DAIMON"









Cause and effect and regression monitoring

Multivariate monitoring Unknown relationships

Univariate monitoring

All data

Not only process control and quality tests (particle size, hardness, dissolution, etc.) but **all** variables, including raw material attributes and manufacturing parameters (pH, viscosity, product temperature, etc.)

Confirm the **known relationship** by fitting the observations from the commercial production stage to the knowledge accumulated at the research and development stage (e.g., particle size and hardness affect dissolution)

Known relationships

Efficient and effective detection of multivariate change by models; prediction and advance detection of risks by finding unknown relationships

All manufacturing has a common essence, regardless of modality

→ Apply the systems and extensive knowledge gained
with small molecules to biopharmaceuticals as well

This slide is a bit difficult. It's about statistical analysis.

You see on the left, univariate monitoring. We are looking at all data.

Please take this example as temperature monitoring. Let's say that we are measuring the temperature of the solvent, and we are trying to monitor it so that the temperature would not fluctuate so much. This is a simple type of monitoring.

In the middle is the confirmation of the non-relationship. For example, solubility to water. In order to evaluate that, if it's known that at the R&D stage that the size matters to solubility, we will be monitoring the size of the particle, as well as the hardness. If there are no relationships according to the data of R&D, we will be capturing that, and utilizing it; we will be predicting for the purpose of quality management.

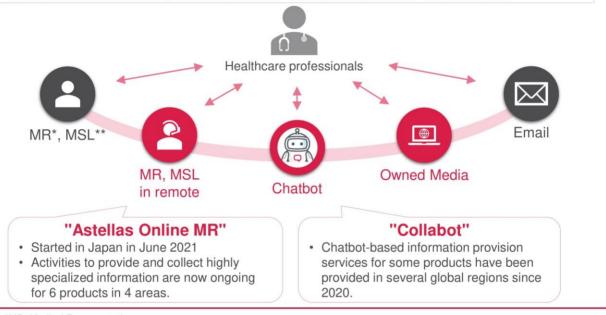
On the right is multivariate monitoring. At the R&D stage, there may be some data elements which have unknown relationships. During commercial manufacturing, we will be taking a lot of data at the same time, and we will evaluate the relationship of those data elements. If we find that there is a high correlation, we will be managing the data with the combination of various data elements.

So, we have a system which we have built with low molecules. But regardless of mentality, the manufacturing concept is the same. So, we would like to roll it out to biopharmaceuticals as well.

Omni-channel communication to revolutionize the customer experience



- Properly providing information to healthcare professionals and collecting information from them is an
 essential part of contributing to the treatment of patients.
- → Use digital channels to pursue timely and appropriate provision of information



*MR: Medical Representative

**MSL: Medical Science Liaison

I would like to go to page 29. From here, I would like to talk about marketing.

Omni-channel communication to revolutionize the customer experience.

We developed ethical drugs. We provide the product to the patients, but we go through the healthcare professionals so that the health professionals can have confidence in prescribing the drug to their patients.

We need to have a close communication with healthcare professionals. Due to COVID-19, it is very difficult to have communication face-to-face. The MRs, MSLs, they go to the healthcare professionals, but healthcare professionals are there to meet the patients, not MRs or MSLs. So, we would like to conduct communication utilizing online methodologies.

I would like to give you an example of the middle three.

The left is Astellas Online MR. Online MR is something that we have agreed with Dainippon Sumitomo Pharma as a trademark. We started using this in June of 2021. This is an online MR activity with high expertise.

In the middle is chatbot. We have named it Collabot. In 2020, we started the communication that we are able to provide information 24/7. We are providing the service in Japanese, but the platform is global. We are using the same platform for a different product in a different language. We are rolling out our business in more than 70 countries around the world.

When we create the chat system, we are able to roll it out to other countries, and we can modify it to meet the regulations of other countries as well. We would be able to supplement the explanation that is given by MRs, while they are under training, for example. We are utilizing this to more easily roll out our products around the world.

As for the third point, Owned Media, we have Astellas Medical net. This is for HCPs, and we provide product information. It's a website.

In April of last year, we have had a renewal. So Owned Media itself is not new, but by renewing it rather than just providing the information that the pharmaceutical companies want to provide the doctors, we would be able to grasp at the doctors would like to know, and also by utilizing the chat, we would be able to provide the information to the doctors. So multichannel is now being used through this initiative,

There was an increase of visitors by 31%. And also, the Web Symposium page visitor increased by 117%.

Automation of pharmacovigilance activities 32 Adverse event (AE) information is reported 24/7 from patients and healthcare professionals around the world AE information collected must be entered into a safety database for assessment, monitoring, reporting to regulatory authorities, and planning of safety measures. → Automate capturing and processing of vast amounts of information, which could further contribute to patient safety Phase1 AE info. Capture, Risk Mgmt., Signal Compliance Workflow & Case Medical Review **Processing Enhancements** Case Intake Detection Reporting AI, RPA, etc. Receipt of AE information A single point of entry Identifying new and additional information for information Data capturing · Labor saving of data entry · Minimize data entry errors Convert to unified electronic format · Shorten processing time Expected cost savings of several hundred million yen per year

*Pharmacovigilance: Activities relating to the collection, assessment, reporting of safety information on pharmaceutical products to regulatory authorities, planning and execution of safety measures.

when the entire system is operational in 5 years.

I will be skipping to page 32, pharmacovigilance activities automation.

Pharmacovigilance is something that collects information about side effects and also other information about the adverse events, which may have occurred during the use of that drug. It may not be related to that particular drug, but we collect those kinds of safety information, and we evaluate it.

That is the pharmacovigilance activity.

We collect information from the HCPs, as well as the patients from around the world. There is complete information, incomplete information, but we are getting the report 24/7. This is information that's related to the safety of the patients, and we need to process the vast amount of information in a short amount of time.

Support

Japan 03.4405.3160 Tollfree 0120.966.744 There are areas in which the experts must handle, but there are areas the robots will be better at doing. So as Phase I, the input of the safety information is now being verified. After the receipt of the safety information and registration.

So, AI, RPA are being utilized for automation purposes. Through this, human error which may have occurred has been improved, but we don't know the exact effect of this yet. But upon the completion of Phase I -- well, there are many people who are involved in this, and by replacing it with digital, we believe that we can reduce the expenses by hundreds of millions of yen each year.

In addition to that, because this is a safety information related to patients by processing it accurately in a short amount of time, we believe that it would be beneficial for the patient's side as well.

Establishment of "Apple", a company-wide enterprise business platform



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Purpose	 Utilization of common master data and business model Standardized strategy, KPI Monitoring and HR data management 			
Target	Function	Personnel	Sales management	
		Accounting	Supply chain	
		Procurement	Strategy/Network/Planning	
	Region	Global		
Effect	 Turning data into assets: for more accurate forecasts and strategies Flexibility: immediate response to changes in external environment Efficiency: focus on work with higher value added Resolving complexity: minimizing business risk 			



Up to here, I have been talking about the value chain. From here, I would like to talk more about back offices. I would like to talk about establishment of Apple, a Company-wide enterprise business platform.

In the past, the enterprise business platform existed regionally. We were using SAP, and we decided to integrate the regional SAP into a global platform using the common master data, the common operation, and based on that, we would be able to use the common data globally.

All of the transactions will be integrated into one enterprise business platform, and we can accumulate it as a Company' asset. From there, we would be able to make more accurate predictions, and it can be used for strategic decision-making. We would be able to improve the efficiency of the global operation.

At the same time, we would be able to work on outsourcing. Personnel, accounting, procurement, sales management, et cetera, are functions, which are integrated into this enterprise business platform.

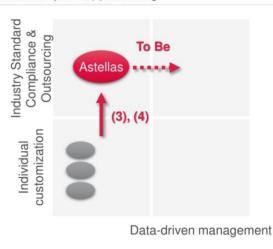
Establishment of "Apple", a company-wide enterprise business platform



- · A core business system based on the SAP system has been established, implemented, and transferred to the cloud
- Astellas is one of the few pharmaceutical companies worldwide that have implemented all of the following at once and completed their introduction to the three main regions

(1) SAP version upgrade, (2) global integration, (3) industry standard compliance, (4) outsourcing





Aim for data-driven management by leveraging the advantage afforded by a world-class base



This is the discussion about the system.

The personnel, accounting, procurement, SAP system has been globally integrated. As you can see, the global integration, SAP version upgrade, from the customized SAP, it moved to the industry standard system and also outsourcing. Those four things have been rolled into one for implementation.

In the three regions of US, Japan, and EMEA, we have been able to roll that out, and we are unique in that aspect. The SAP, which was put into the data center, we decided to put it on Microsoft Azure, a Cloud-based system.

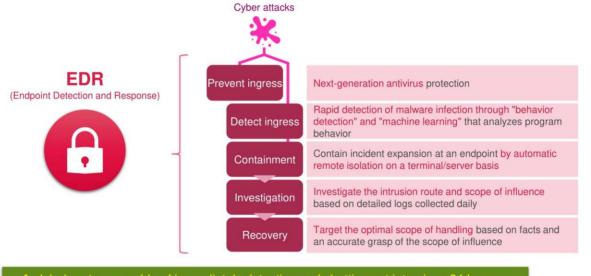
In other companies, I think that they may do it in the four stages, but we did it all in one go. We worked on this from 2017. In the US, Japan, and in Europe, the system has already been implemented, as it says on the right.

Going forward, all of the transactions will be integrated into one location. From the management perspective, it would be easier to make a prediction about the future business. By utilizing this, Astellas would like to evolve into a data-driven company.

"Protection" DX: cybersecurity



- Cyber attacks on the medical industry are very common, and intellectual property theft and demands for ransom payment, etc., are disrupting to business
- → Cybersecurity must be constructed to support business and strategy realization



A global system capable of immediately detecting and shutting out intrusions 24 hours a day, 365 days a year, has already been established



Last but not least is the protection DX cybersecurity.

I have been talking about the value chain, as well as the mission-critical system. We are handling vast amount of data, and we are operating mini systems, and that's being used globally. But the threat of cybersecurity is increasing every day. Cyber-attacks are becoming more sophisticated, more malicious, and the cybersecurity activities are a never-ending activity.

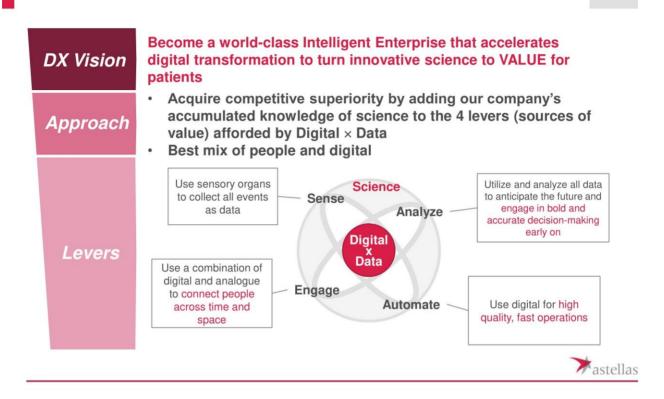
Inclusive of the pharmaceutical company, the healthcare industry is always subject to cyber-attacks because it handles very important data, and there are some ransomware attacks to this industry. To prevent that, we are working on cybersecurity activities.

We are working to prevent the invasion, but we would not be able to prevent everything. We would like to strengthen cyber resilience where we would be able to detect the breach early and suppress it.

As we discussed in the remote work issues, under COVID-19, PCs are not necessarily in a protected environment, so endpoint detection and response system has been rolled out in our company as part of our cybersecurity program. We have EDR in place, and we have outsourcing. 24/7, when there is a detection, we would be able to respond to it globally.

If there is a breach of malware, if that happens in Japan or elsewhere, we would be able to take initial response right away in the same manner.





Last but not least is the digital ambition slide, the best mix of human and digital.

As I said at the beginning, digital transformation is about AI, data analytics, and utilization of digital, but that is merely a starting point. From there, there needs to be an evolution where digital is good, and where people are good. These two must supplement each other. We need to capitalize on each of the strengths, and that would be the best mix.

In Astellas, we would like to add on science and mix that with the best mix of digital and people. That would be the key for Astellas to become a world-class intelligent enterprise.

That will be all for my report. Thank you very much.

Fujii: That is all. The presentation is completed. We will now take questions.

Question & Answer

Fujii [Q]: First question. Securing the digital human resources. What is your view? What kind of talents are you looking for and hiring external talents or promoting, developing internal talents?

Suda [A]: Thank you for the question. Digital talents, digital human resource, data scientists, is one group and digital transformation, the transformation promoter, is another group. Data scientists, this is not something we can outsource. And so, we will develop and promote such experts internally and prepare the environment for them to fully exert their capability.

Now, data scientists are not abundant around the world. Compared to other industries, pharmaceutical industries may have a little more, but we are still lacking. Data scientists and statistical analysts, personnel, those who are well versed with life science, this is very rare.

Those are the kind of data analysts in digital transformation that we need. They are not to be outsourced. We will [recruit] with universities and academia and appeal ourselves as the attractive employer, that we can offer opportunity, and that we are an attractive company. We introduce ourselves to various schools and use events to attract the attention of data analysts, data scientists.

On the other hand, those who promote the digital transformation, Astellas Pharma is a pharmaceutical company. We do not need experts who have specific technical expertise, but we need the person to understand the value and how to apply that internally.

The idea should be promoted as projects and not just introducing the digital in our business but using it to transform our business. Transformation means business transformation using digital. We want people who can promote the transformation. It's not the Information Systems department. The key people in the business divisions will lead this endeavor as key leaders. We are not doing this sufficiently yet. But through various projects, we will develop such talents and technical experts. We have experts outside of the Company, so we will collaborate effectively. The outsource and in-source will be combined as we move forward.

Fujii [Q]: The second question. You talked about Project Apple. In the structure of Apple, how was there an evolved evolution of the performance management in the working on CSP? Is the system working towards improvement of the cost reduction?

Okamura [A]: The answer to the question is, in Europe, we had three-stage implementations, and we just completed the third implementation. Mr. Suda emphasized the point that it was working really, really well. But regrettably, at this point, it has not completely contributed to the reduction of the cost in terms of the performance. But the introduction, of course, is the biggest burden.

I think there was a lot of burden to personnel resources. But once we are able to overcome it, where things had to be done regionally, it is now being integrated to a globally common platform and the common operation process is being used, and everyone is on the same page in terms of the data. This improves the efficiency on a daily basis in terms of the operations going forward.

It is not just about the reduction of the human resources who are involved in the work. In the past, if the end-to-end process took one month for decision-making, it may be reduced to several days, if not one day. And the quality, it would not be compromised. So, our goal is that the operational model would evolve like that.

In the financial results briefing, it would take more time to give you the idea of how effective Apple was.

Fujii [Q]: Moving on to the next question. The platform development that you addressed today, this requires big management resource. By doing this yourself, you can have differentiation or distinct unique value. But on the other hand, if you buy off the shelf or collaborate with other pharmaceutical companies, you can pursue another option. How do you decide on these different options?

Suda [A]: Pharmaceutical companies have much regulation. In areas under heavy regulation, we should go for industry standard system rather than trying to exert our distinctive uniqueness. Recently, there are more Cloud systems that are becoming industry standards, so we actively utilize them.

For example, the submission-related document management, the clinical data management, and the safety information management system, we have heavy regulation. Rather than trying to be unique, we use the industry standard Cloud and align ourselves with the industry evolution. But when it comes to research, as I mentioned earlier, in drug discovery, there are many areas we need to compete.

We need to take in what does not exist in the world yet. And so, rather than using the industry standard system, we use the parts, the components, and combine them in an Astellas way, distinct way, and build a platform that does not exist anywhere in the world. That is our unique approach.

Fujii [Q]: Next question. This is for Mr. Okamura. Drug discovery, manufacturing sales on the value chain, I believe that the promotion of digital usage is being done. Maybe you would need to establish a new company which handles the digital aspect. Do you think that would be a potential?

Okamura [A]: Thank you for the question. I would not be denying that. Together with Mr. Suda, who's sitting next to me, advanced informatics and analytics, this is the data science-focused department. Mr. Suda's department is working on the implementation of the IT systems and how best to capitalize on the departments that we already have is at the top of my mind. So more than establishing a new company or using a dedicated vendor, it is not about formalities. We will be selecting what is the best for each initiative. So, we want to be flexible. That's my current thought.

Fujii [Q]: Thank you. Next question. DCT. Slide 23, please. You can see DCT, the direction you are aiming for in three to five years, it says. So much knowledge that Astella is pursuing. Do you want this DCT to be the mainstream going forward?

Okamura [A]: The ideal state of the platform that Astellas uses and each and every clinical trial schedule is different, and remote clinical trials are suitable for some and not suitable for others. What we show here, ideal state in three to five years' time, this is for a remote clinical trial by Astellas, we have a platform that is already self-sufficient by itself and be usable.

That is what we want to achieve in three to five years' time that is complete within a single application. Now not all clinical trials may come on to this platform. That's a different story. In the design, the utilization of this platform is one big factor, and we want to pursue appropriately.

One concrete example is, as you know, we have the cell medicine and the genetic therapy transplanting cells. Cell transplantation procedure cannot be done at home. We have to have the patients come to the site and do this surgically. But after that, the patients do not need to stay in the hospital for a long time. They can go home and lead their daily lives and the data can be gathered appropriately and timely and the analyze timely and accumulated in the database.

This diagram that Suda-san just has shown, once the platform is complete, then we can use parts of clinical trials or the entire clinical trials on a case-by-case basis, wherever we can use it so that our healthcare professionals and the patients will have less burden and a platform that can pursue high-quality clinical trial. That is what we are aspiring for.

Fujii [Q]: Thank you very much. The next question. Slide 20, please. This is the drug discovery platform. You are able to shorten the time as much as 70%. Which is the average? Is it closer to 70%? If it's close to 70%, it's a huge improvement in productivity. But do you think that there would be an increase in the drug compound which would go into the pipeline? And when would we see the increase in the pipeline?

Suda [A]: In terms of the calculation of the 70% reduction in our Research Institute from 2010 to 2019, it took about two and a half years for research and using the system, we were able to realize that in six months. So that is the basis for this calculation of 70%.

How this would be impacting the pipeline? That will be seen afterwards. But the success rate of the research, I said that it is 1 in 10,000 or 30,000. In 10 to 20 years' time, we want to be able to narrow down the number of the candidates at an earlier point so that the efficiency will be improved. We are hoping that the drug discovery platform will be conducive to bringing the Hit compound, to the candidate compound. That would lead to the shortening of the time frame of the research overall. So how that would be reflected in the pipeline, I would not be able to answer that question.

Okamura [A]: Please think of it this way. On this slide, before the things come into this slide, there is an idea. There is a biology which is targeted. There would be identification of one Hit compound. If we put it on this platform, what took two years would take six months to get to that.

So, to your question about whether there will be an increase in the pipeline, from one Hit compound, we are not trying to increase the number of compounds coming into that. It's a different story.

In terms of the contribution, one is that there is less resource needed. Because of the resource constraints, even though we had 10 ideas, we were only able to work on five. But through this platform, we may be able to do all of the 10, and we may be able to enrich the pipeline as a result of that.

In the past, because humans were working on this, sometimes people gave up or there was a mistake made, and there may have been positive or negative judgment made, but if we use this new drug discovery platform, we may be able to have appropriate results, which may lead to an increase in the success rate.

It is not just about shortening the time frame. We may be able to test out something that we were not able to do before. And also, the data which were conducive to misjudgment that will be corrected to a high-quality data that would be conducive to improve decision-making.

Just like the DCT platform that was discussed, this platform cannot be applied to all of the programs. For now, it is for the low molecule and also something that robots can synthesize and how it could be utilized in antibodies. That will be a discussion for the future. That's our dream.

But our assumption is that we will be using it for low molecules. But just because we have put this drug discovery platform, we don't believe that the pipeline will be double the amount than before. But because we have been able to shorten the time to get to [candidate] compound, we may be able to capitalize on this, and we may be able to introduce something that has come out of this platform soon to the investors.

Fujii [Q]: Thank you. Next question, slide 7, please. Measures that will reduce the development costs are mentioned this time. On page 7, on the VALUE page, it says cost. What kind of impact do you anticipate on cost, the pharmaceutical drug price will go down?

Okamura [A]: Thank you for the question. Yes, for the healthcare system, the drug price is cost. So, the simplest way to reduce cost is to reduce the price launched in the market. That will reduce cost. I understand that logic. But that is not what we are mentioning here.

For example, until now, with hospitalization, long-term hospitalization requiring treatment can shift to the same treatment at home, a drug that will make it possible for treatment at home. And where you needed to come to the hospital for three years may change to one big visit to the hospital but then just visiting and keeping the same level of health once a year -- just visit once a year.

Or, if you have to support a family member, quit your job, and support the family member, it will be a burden, but we hope that kind of burden can be alleviated through drugs. There are various discussions on the drug price.

Access to health, access to medicine is being addressed as an industry and as Astellas, we have to think about this more. VALUE, of course, each and every product outcome should improve. But even if the outcome is good, it will not lead to VALUE, unless it is effectively used.

So not just focusing on products with great outcome, but also make it accessible to many patients. This will lead to VALUE, and we are well aware of that. That is what we are trying to do.

Fujii [Q]: Thank you very much. The next question is related to Mahol-A-Ba. It seems that you are utilizing the robotic technology. But how are you utilizing it in the manufacturing process? In Mahol-A-Ba, you're utilizing robotics. The question is, in the manufacturing, how are you utilizing the robotics? Any ideas?

Suda [A]: In the commercial production, mass production is conducted. There is a manufacturing facility dedicated to manufacturing, and the area where it's beneficial to utilize the system like Mahol-A-Ba is to replace people with robots or have robots support people.

In utilizing robots in manufacturing sites, one point that we need to think about is how it can be utilized in the mass manufacturing process in cell therapy, in which Astellas is focusing on. We do try to do mass culture of cells, but it's more about precision medicine, individualized medicine. We would not be using a large-scale facility but use robots for the individualization of medicine. There is a higher possibility there.

Fujii [Q]: The next question. The utilization of real-world data, your unique initiatives, or the value creation you have in mind, please?

Suda [A]: In the value chain, this is from research to marketing, to the reimbursement, it is utilized in broad areas. Whether we have something unique about ourselves, one is, in the global axis, I mentioned that the Company is operated on the global basis. This real-world data is mainly used by advanced informatics and analytics. This has global capability.

When we say real-world data, personal information is one aspect. One [set of] information cannot be used around the globe in some cases. So, if this function only exists in Japan, it is not useful, or if this function only exists in the US, it cannot be useful. AIA has a global reach. So, in that case, this can be utilized in the region and shared globally.

This is how we can use the value of real-world data to the R&D and for our products. We think that is one unique feature we have about our company. If we only use real-world data only in research and marketing, that is not the case. We use all kinds of possibility about one data in all kinds of domains, not just a single domain.

Okamura [A]: I often hear that things are sometimes difficult. But what I expect of real-world data is, maybe this is not unique about us, but the virtual arm in the clinical trial.

Unlike in the past, the rare disease or limited patient segments, shifting gears to drugs that directly match rare diseases. So statistical analysis, it is difficult to gather the patients that is sufficient for the statistical

analysis. For those who are already severely ill, using placebo as a comparator is ethically not viable. In most cases, the progression of the disease is mild and slow.

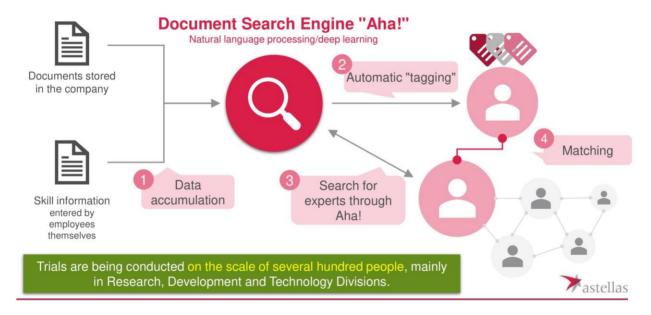
So mildly progressing disease, to find the difference there, we need a long period of time and a large number of patients. My message is, if we develop real-world data sufficiently and the patients with the drugs and those who are applied real-world data be applied to the clinical data, I think that will be very ideal.

The enrollment period has been long until now. But if possible, once the inclusion exclusion criteria is set, we want to pull the patients from the real-world data and understand where those patients are located. If we can identify that, then the enrollment period can be shortened, and the drug can be delivered sooner. That is just still high in the sky.

Internal Talent Search System "TAKUMI"



- There is a need to quickly find experts within the company, assemble teams, and have them work on solving problems
- · In the remote work environment, it is more difficult to form new work relationships through casual interaction
- → A tool to actively search for employees who have the experience and knowledge wanted



Fujii [Q]: Thank you very much. The next question is related to the TAKUMI experts. The TAKUMI system for the talent search. When will it go into full-scale implementation? Would that be applied to the digital-related departments as well?

Suda [A]: Could you show the slide, please? This is number 36, which I skipped during my presentation.

As you can see, in the R&D area, et cetera, we started piloting this. This is not a talent management system that's being conducted in HR. This is a search engine where individuals would be able to make an appeal of themselves. It is not an HR system.

Phase I, the pilot stage. We have conducted a trial in the scale of several hundred people, mainly in R&D and Technology Divisions, and the talent pool, which is being accumulated. In the past, those talents could not

Japan 03.4405.3160 Tollfree 0120.966.744 have been found. In starting a new project, there should be someone who has the experience of this when we have 15,000 people globally, but we were not able to identify those personnel.

It was just a word-of-mouth communication to get to those talents. Using this internal talent system internal talent search system, TAKUMI, we are trying to identify those individuals. When a project starts, the project team would be able to access TAKUMI to find experts that they need.

This year, as Phase II, we will be increasing the number of functions participating. Also, we would like to roll it out globally.

On the digital side, the people who are residing in various functions may believe that, even though they belong to the sales function, they may like working with AI, and they may be in a submission department working on submission. But because they are handling a vast amount of documents, they are personally learning the natural language processing. There may be some people who have been transferred from the R&D department to the other department, but they have expertise skills that can be utilized in some projects.

This system, TAKUMI, would enable the identification of people who have the talents, which are hidden. As one use case of this talent search system, we would like to include digital, and the Digital Promotion department should be looking for talents who have expert knowledge in that area or identification of people who are very much interested or people who are studying those fields. We want them to input their information in the search engine.

Fujii [Q]: Thank you very much. Next question. Slide 15, please. We talked about the levers. Analyze, engage, automate. I understand these three. How do you plan to leverage sense? Could you elaborate?

Suda [A]: Thank you for the question. Sense means sensor. In the earlier example, DAIMON, in the manufacturing process, you get various types of data. This data is gathered. So that is the starting point of analyze. Mahol-A-Ba and Human-in-the-Loop drug discovery platform is another example.

The test data experiment data needs to be gathered. Traditionally, animal movement, will it be activated with the drug administration? We had numerical data. We were focusing on getting numerical data. But now we can watch the animal's movement by video and through image processing. We can translate that to the movement of the volume of animal. And so, various circumstances can be gathered as data. Rather than eyes, we can use image processing using a camera. That is one example.

Fujii [Q]: Thank you very much. The next question. Earlier, you talked about the best mix of humans and digital. I would like to have supplementary comments from Mr. Okamura as well.

Okamura [A]: Digital is becoming predominant, and everyone is talking about digital transformation every day these days. And the first response is resistant and fear, and especially people in my generation may fear that their work is replaced by machines.

The people who believe that their digital literacy is low, they feel that they are losing their place. That's why they are resisting digitization.

When I talk with those kinds of people, I always say there are areas where machines are good, and where machines are not good. And there are humans. There are areas where humans are very good. The area where machines are good, we can leave it with them. Humans can concentrate on where we are good. As Mr. Suda mentioned, digital equipment would be able to do things highly accurately with high speed, without fatigue.

What used to be one could make 10, 100,000, 10,000, but they cannot make zero to one. If they can do that, that would be a world of singularity, and that would be SciFi. But the area of making zero to one, that's the

area humans must always intervene. The designing of the compound, testing it and feeding it back, there always needs to be human intervention in order to create something that's radical. So, what I say is to leave it to the machines, what machines are good at, and we should be doing what humans are doing best.

Fujii [Q]: Thank you very much. Next question. Earlier, you talked about drug discovery robot utilization. The uniqueness of Astellas. Could Suda-san explain?

Suda [A]: Yes. Please display the screen. This is one example. On the left side, you can see Mahol. This is a product. This can be not Astellas, and doesn't need to be Astellas. It can be used anywhere. On the right side, this equipment, devices are also sold. So, each and every component, devices can be used and introduced by any company.

What Astellas is doing is I talked about four levers. The science expertise accumulated in Astellas is added to the four levers to exert the competitive edge. So, these robots as parts, and AI as parts, using science expertise are combined, and the platform is built as a result of that. This is where Astellas is using its expertise in trying to do what others cannot do.

This Mahol-A-Ba on Mahol plus A Astellas and BA, which is platform. That's the word that we made up. This Mahol, which is the expert arm, and the function-specific device are combined from Astellas' unique viewpoint so that it can serve as the unique expert eye. So, by combining arm and eye, we combine the AI as a platform. This expert combination is Astellas' unique distinctiveness.

Fujii [Q]: Thank you very much. The next question. You talked about broad digitization at your company. What are the challenges that you're facing? What have you identified?

Okamura [A]: Let me start. It is not just about Astellas, but the trend of digital transformation, the wave of the digital transformation, that has come to all of the functions. If it had come gradually, we would have been able to work on one by one. But when the wave comes all at once, we are not able to work on everything at one time. We need to prioritize. And we have a resource restriction because we need to prioritize.

The R&D in ethical drugs takes a long time. There is a gap in the speed of the evolution of AI, et cetera. At the time of the submission of the drugs, the data that we have accumulated inclusive of the clinical trials and another call data. But rather than submitting the data today that would be submitted several years later. In that several years' time, the methodology of the analysis of the data would have advanced. So, the data from AI five years ago, would that be accepted five years later, in the case that programming is used, so after the submission, the credibility of the data analysis, that can be reproduced.

But in terms of AI, it is always learning. It cannot go back to the time of the analysis and because it would have learned. So how the submission documents can be proved as appropriate, how that would be evaluated? I think that's one challenge that we may need to tackle in the future.

I would like to talk from a nontechnical perspective. I think that the emotional side is something that would be a challenge for a pharmaceutical company to proceed with digital transformation. Pharmaceutical companies are a highly regulated industry, and they cannot make mistakes because the health and the safety of the patients are in the pharmaceutical companies' hands.

The iterative methodology must be used for digital methodology. But in the pharmaceutical companies, it tends to try to create something that would not make mistakes. The senior people cannot get rid of that mindset because they have been doing that for a long time. So, in terms of digital methodology, we need to start small with pilot, and how we can expand that is a challenge.

Fujii [M]: Thank you very much. It's passed the scheduled time, so we would like to close with the earlier one as the last question. For the questions that we could not answer in this time, we will respond through our people in charge later.

This concludes today's media briefing. Thank you very much again for your attendance.

[END]

Document Notes

- 1. Portions of the document where the audio is unclear are marked with [Inaudible].
- 2. Portions of the document where the audio is obscured by technical difficulty are marked with [TD].
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