**Astellas Pharma Inc.**

Media Briefing "Astellas' Digital Transformation with Data Analytics"

March 27, 2023

# Event Summary

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| **[Company Name]** | Astellas Pharma Inc. |
| **[Event Language]** | JPN |
| **[Event Type]** | Media Briefing |
| **[Event Name]** | "Astellas' Digital Transformation with Data Analytics" |
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| **[Date]** | March 27, 2023 |
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| **[Venue]** | Webcast |
| **[Number of Speakers]** | 2 |

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|---|---|
| Naoki Okamura | Representative Director, Executive Vice President and Chief Strategy Officer (CStO) |
| Masanori Ito | Senior Director, Advanced Informatics & Analytics |

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# Presentation

**MC:** Thank you very much for your participation for this meeting of Astellas' Corporate-wide Digital Transformation Driven by Analytics, despite of your busy schedule. I'm Hiro Ikeda, the Vice President of the Corporate Advocacy and Relations Division.

Now we would like to start the webinar on Astellas' Corporate-wide Digital Transformation Driven by Analytics. First, let me explain you how to ask the questions for this session at the end of this meeting. On the right side of the screen, you can find the question form, so please use it. Even during the presentation, you can ask the questions. If there are similar questions gathered in a multiple way, then we are going to ask the question in a summarized manner. This material is available on the website and in line with the presentation material, we would like to go through this seminar.

The participants here today are the CStO, Naoki Okamura; and also Senior Director of Advanced Informatics & Analytics, Masanori Ito, so there are two speakers here today.

## Cautionary Statement Regarding Forward-Looking Information

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In this material, statements made with respect to current plans, estimates, strategies and beliefs and other statements that are not historical facts are forward-looking statements about the future performance of Astellas Pharma. These statements are based on management's current assumptions and beliefs in light of the information currently available to it and involve known and unknown risks and uncertainties. A number of factors could cause actual results to differ materially from those discussed in the forward-looking statements. Such factors include, but are not limited to: (i) changes in general economic conditions and in laws and regulations, relating to pharmaceutical markets, (ii) currency exchange rate fluctuations, (iii) delays in new product launches, (iv) the inability of Astellas to market existing and new products effectively, (v) the inability of Astellas to continue to effectively research and develop products accepted by customers in highly competitive markets, and (vi) infringements of Astellas' intellectual property rights by third parties.

Information about pharmaceutical products (including products currently in development) which is included in this material is not intended to constitute an advertisement or medical advice. Information about investigational compounds in development does not imply established safety or efficacy of the compounds; there is no guarantee investigational compounds will receive regulatory approval or become commercially available for the uses being investigated.

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This material or oral presentation by representatives for the Company and answers and statements by representatives for the Company in the Q&A session includes forward-looking statements based on assumptions and beliefs. In light of the information currently available to management and subject to significant risks and uncertainties, actual results may differ materially depending on the number of factors. They can contain information of pharmaceuticals, including compounds under development, but this information is not intended to make any representations or advertisements regarding the efficacy or effectiveness of these preparations.

All sessions including Q&A will be held in Japanese, but simultaneous translation into English by interpreters, accuracy cannot be guaranteed. Thank you.

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# What Astellas is Aiming for with Corporate-wide Digital Transformation

**Naoki Okamura**, Chief Strategy Officer



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**Okamura:** Thank you very much, Hiro-san. Hello. I'm Chief Strategy Officer. My name is Okamura. Thank you very much for your time today.

Last year, digital transformation, how to utilize it in our business, inviting Shinya Suda, head of Information Systems, we talked about how we are going to use it in our business (*Learn more at here). Before digital transformation can be used not only for the business at the practical level, but we can use analytics technologies for corporate-wide management and also the business decision-making to enhance the quality, and that's what we would like to talk about today.

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## VALUE Creation
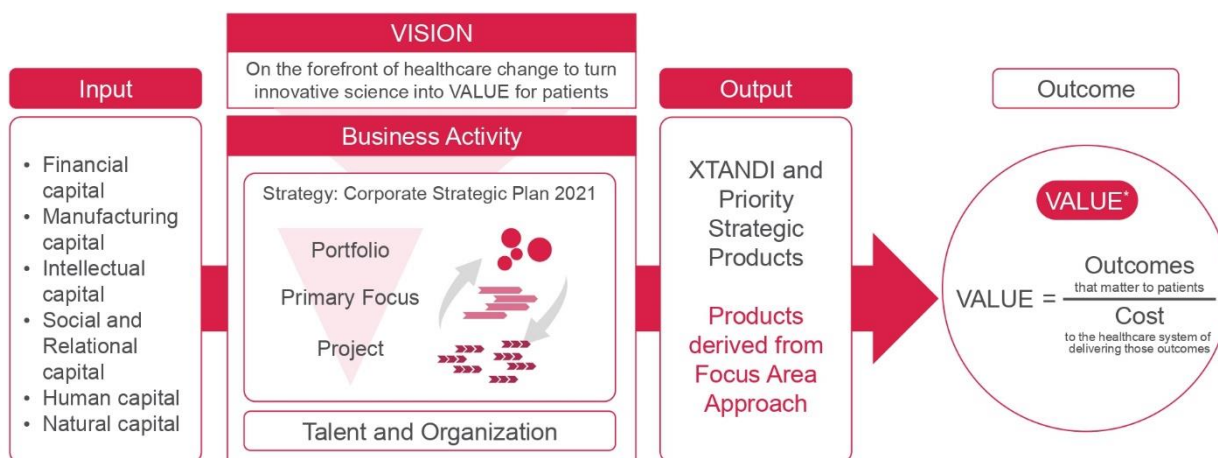
*Adapted from "What Is Value in HealthCare?" Porter, M.E. (2010). New England Journal of Medicine

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This page shows our VALUE creation model in a very simplified manner.

We have been repeatedly saying that our VISION is to be on the forefront of health care change to turn innovative science into VALUE for patients. We have to define this VALUE. Otherwise, we have 15,000 employees globally, and they may do their work in a different direction.

As you can see on the right, we have the VALUE and VALUE in all capital letters in English, we are defining what we call VALUE here. The numerator is the outcomes that matter to the patients, and the denominator is cost to the health care system of delivering those outcomes. It's not the cost to be paid by Astellas. So this is the return on investment.

Based on this VISION, we create VALUE to be offered. So right now, to do so, we have a five-year CSP2021, Corporate Strategy Plan 2021. We have XTANDI and the Strategic Products to follow as output. That's one major group. In the medium term, they are going to be our growth drivers. But for the future, continuous growth will be generated by the following source of VALUE. In core, the Focus Area Approach, we will have a new product derived from Focus Area Approach as future growth drivers.
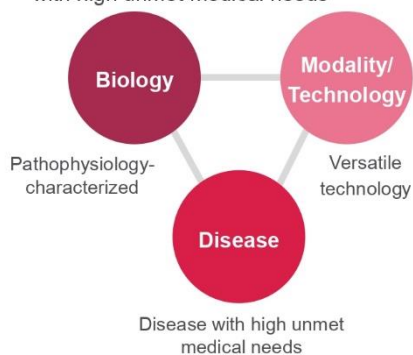


**Astellas R&D Strategy**
Analytics to turn innovative science into VALUE

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**Focus Area Approach**

is designed to identify drug discovery opportunities flexibly and efficiently by combining innovative biologies and modalities/technologies to address diseases with high unmet medical needs

Biology — Pathophysiology-characterized

Modality/Technology — Versatile technology

Disease — Disease with high unmet medical needs

**Primary Focus**

| | Biology/Modality/Technology [1] | Modality |
|---|---|---|
| **Genetic Regulation** | Gene replacement (AAV) | Gene |
| **Immuno-Oncology** | Checkpoint | Small molecule |
| | Artificial adjuvant vector cell (aAVC) | Other |
| | Oncolytic virus (intratumoral) | Other |
| | Oncolytic virus (systemic) | Gene |
| | Bispecific immune cell engager | Gene |
| | Cancer cell therapy (UDC) | Antibody |
| **Blindness & Regeneration** | Cell replacement | Cell |
| | Cell replacement (UDC) | Cell |
| | Gene regulation (AAV) | Gene |
| **Mitochondria** | Gene regulation & mitochondrial biogenesis | Small molecule |
| | Mitochondrial stress | Small molecule |
| | Mitochondrial transfer | Cell |
| **Targeted Protein Degradation** | Protein degradation | Small molecule |

Modality legend: Small molecule, Antibody, Gene, Cell, Other

**Coordinate a portfolio of various possibilities**
**→ Analytics and modeling support this decision making**

1. Not exhaustively listed.
AAV: Adeno-associated virus, UDC: Universal donor cell

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As we have been talking about it many times, what is the Focus Area Approach? I'd like to briefly explain. In 2015, before we changed the VISION, we were using the philosophy, Global Category Leader. In therapeutic areas, we bring our management resources into areas defined by the global category leaders or therapeutic areas such as immunology and implantation and also urology. We have lessons learned there.

Based on the new VISION, we have to follow the cutting-edge biologies and the optimal modalities and technology to change the biology must be sought. The combination of biologies and modalities must be most clear to bring benefits to the patients, so such diseases and patient populations must be identified. And there, our science can bring VALUE or not; we have to confirm.

Instead of coming from the disease areas, this approach from the scientific innovation, various projects are to be generated.

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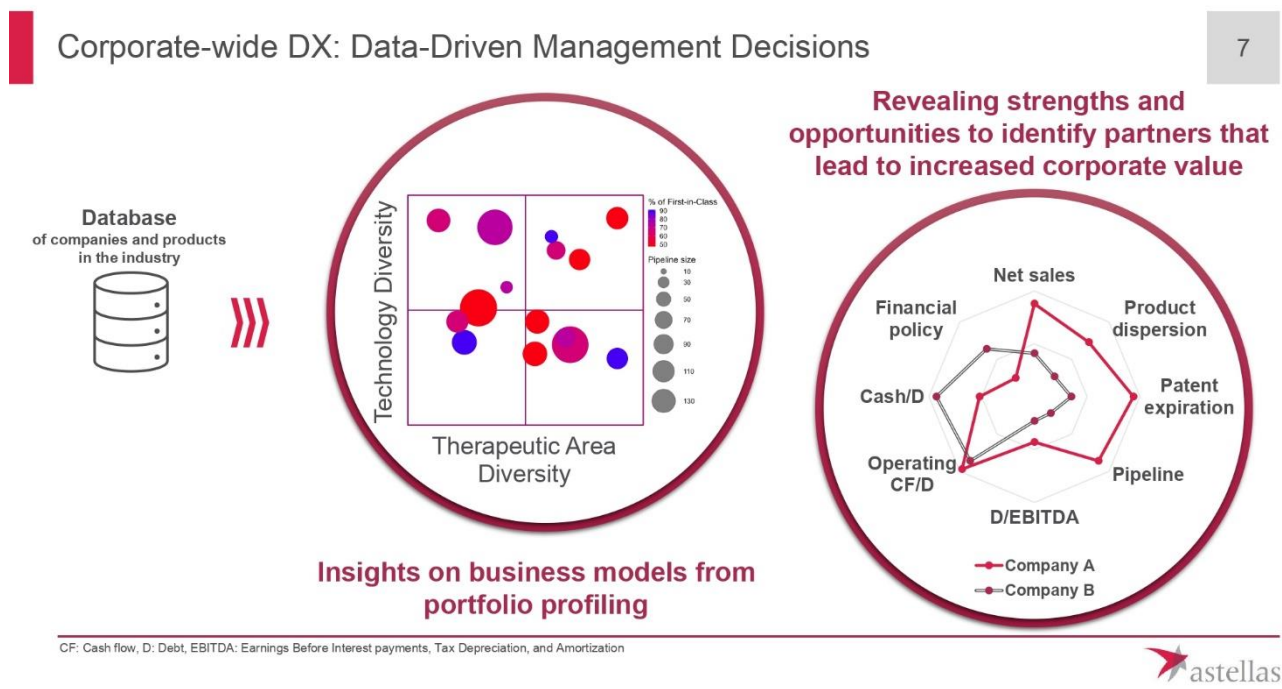| Japan | 050.5212.7790 | North America | 1.800.674.8375 |
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From this triangle, each one of them is to take a challenge on cutting-edge technology, so probably the success or the batting average may be low. But once we are able to have a great triangle, we can generate a lot of great projects, so we'd like to increase the probability of success.

We have a triangle here and if you can bring the project to the clinical stage, that's what we call primary focus. We have Genetic Regulation, Immuno-Oncology, Blindness and Regeneration, Mitochondria, and Targeted Protein Degradation. We have five primary focuses ongoing right now.

Generally speaking, when you evaluate the investments, in that world, cash flow would be calculated and you have to discount with a discount ratio. In a long-term business like us, decision tree will be drawn and decision notes would be applied with the probability of success by adjusting the probability to adapt everything. This is the NPV after a discount on NPV. And when you evaluate a single product, this is a very good way because there is one number. If it's positive, you would go and if it's negative, you don't go for it.

As you can see on the slide, this is the latest science with lots of uncertainties. And they're intertwined with each other. In the same primary focus, if a project fails, the priority will change for other products and also, the priorities among primary focuses will also change. So we cannot really manage just based on a simple VALUE calculation.

We have to take these into consideration. We have to take into account a variety of possibilities to form our portfolio. Analytics and modeling would be essential elements. Experts can perform modeling and analytics, but that's not enough. You have to interpret the results. The management must have such literacy to be able to do so.



Two examples of the data-driven management decisions for corporate-wide DX, this is what we are doing.

We generate these on our own, but we would also purchase a database from outside, which also we leverage. Portfolio profiling would be performed and if we proceed in this vein, what is going to be the optimum business model. We are referring to this for reference.

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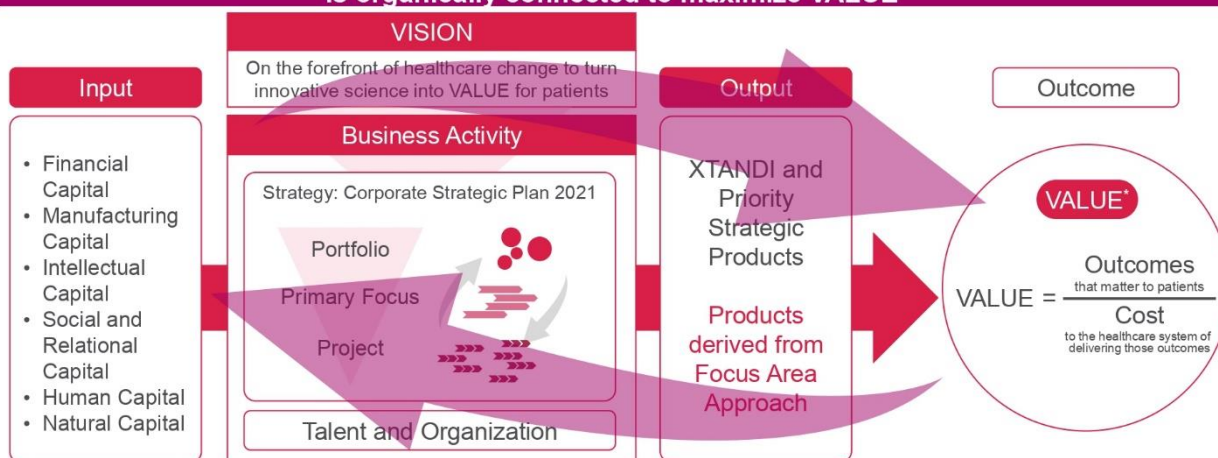| Japan | 050.5212.7790 | North America | 1.800.674.8375 |
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As you can see on the right, in business development, products or companies could be procured from outside. Then with what company, the strengths and opportunities can be brought about in which combination between us and another company. This is a rough valuation, but we can show it with objective data to show it in an easy-to-understand way.

This is going to be business as usual, in our daily conversation, something similar to this can be discussed in our daily activities and the quality of management can be enhanced naturally. That's our expectation.



Going back to the value-creation model I showed you earlier, the most ideal state is a state in which all data from management decisions to individual project is organically connected to maximize VALUE. As you can see on the right, the "VALUE" can be maximized in this way.

Using the cutting-edge technologies to manage the Company and the business, we have just started. So we are far away from the very ideal situation yet. But still, every day, a little by little, we are improving. For better management decision-making and enhanced quality, we are making efforts to that end.

I gave you a rough overview, which may not be interesting for you. Young data scientists are led by the following speaker to enhance the quality of management and decision-making by creating various models and offering the results of analysis. Ito is going to speak to give you specific examples as well as other details. Ito-san, please.

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# Corporate-wide Digital Transformation Driven by Analytics

**Masanori Ito**, Ph.D., MBA
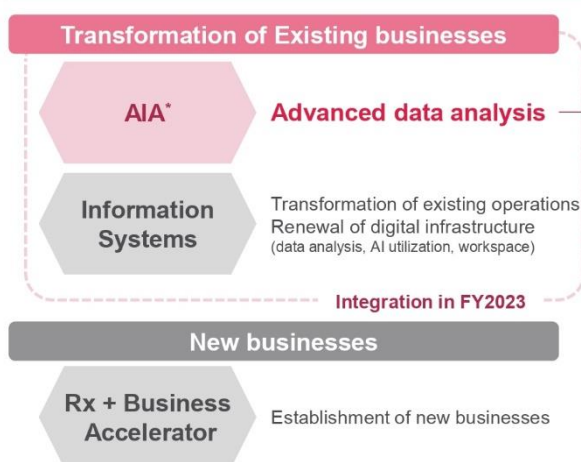Senior Director, Advanced Informatics & Analytics



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**Ito:** I'm Masanori Ito. I belong to Advance Informatics & Analytics and provide solutions using data and analytics to address various corporate-wide management issues internally. My department is mentioned as AIA in the presentation material. Thank you for your time today.

Please show my slide. Initially, I'd like to briefly introduce main divisions responsible for driving digital transformation at Astellas.

## AIA Responsible for Data Analytics across Entire Company 10

**Major divisions responsible for DX**

**Transformation of Existing businesses**

- **AIA\*** — **Advanced data analysis**
- **Information Systems** — Transformation of existing operations Renewal of digital infrastructure (data analysis, AI utilization, workspace)

*Integration in FY2023*

**New businesses**

- **Rx + Business Accelerator** — Establishment of new businesses

**Groups in AIA**

**Enterprise Insights and Digital Solutions**
Supporting the division's strategic decision-making through advanced analytics and modeling solutions

**Real World Data Innovations and Solutions**
Enable data-driven decision-making through innovative solutions leveraging real-world data to generate robust insights at scale and at speed

**Digital Research Solutions**
Promotes and accelerates drug discovery R&D projects using the latest knowledge and technologies related to advanced medical big data, digital technologies, and advanced data analysis technologies

**Technology, Governance and Informatics**
Expands and supports advanced analytical capabilities with technology, governance, and data engineering

\*AIA: Advanced Informatics & Analytics

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The two in the upper-left, AIA and information systems, are responsible for transformation of the existing pharma businesses. AIA is responsible for advanced data analysis and promotes DX by leveraging digital

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capabilities such as AI and machine learning. Information systems is an IT department, introducing IT and digital technologies to promote the transformation of the existing operations and renewing our digital infrastructure. These two play a central role in promoting the digital transformation of the entire Company in collaboration with the various departments and divisions. These two will be integrated in FY2023.

Rx+ Business Accelerator, in the left-bottom, is responsible for the creation of new businesses using digital and nondigital technologies.

Today, I'd like to talk about the transformation of the existing businesses by using analytics, so I will explain AIA in a bit more detail. AIA consists of four groups, each focusing on different areas: strategic decision-making support; utilization of the real-world data; promotion and acceleration of drug discovery research and data governance; and data engineering. I am the head of the Group called Enterprise Insights and Digital Solutions.

I will talk about the example of analytics contributing to our VALUE creation, which Okamura touched upon earlier. Before explaining the Focus Area Approach, let me talk about some of the characteristics of the pharmaceutical industry.
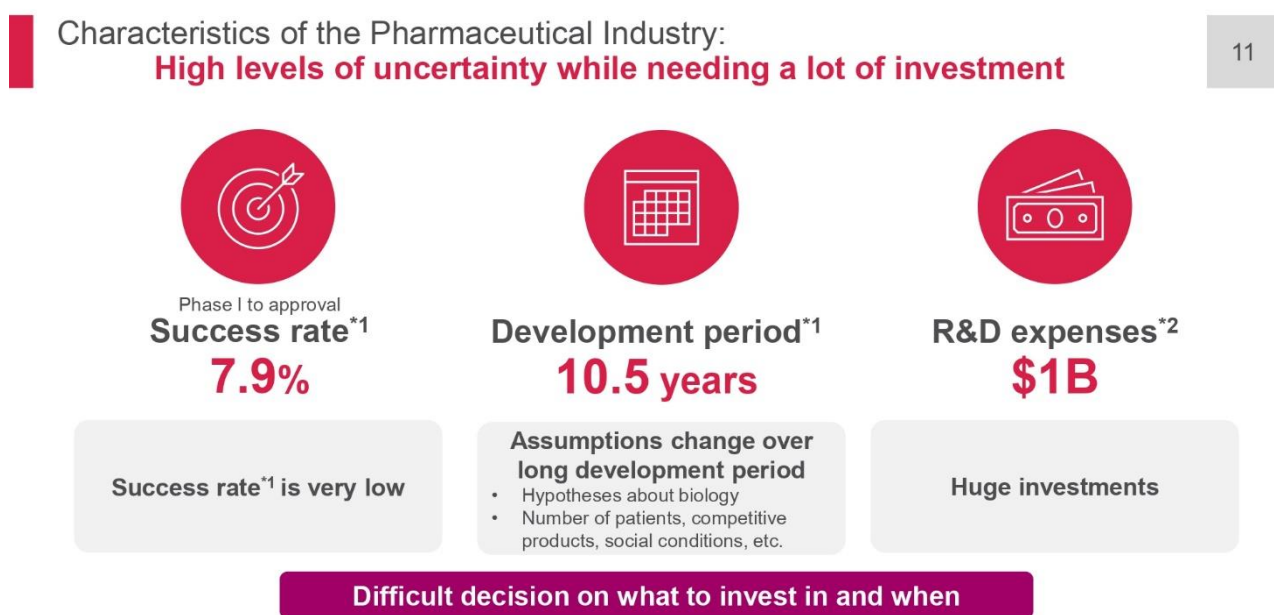


First, this is an industry with high uncertainties. At the same time, this industry requires lots of investment. Drug development takes a very long time, like 10 years or more, and has a very low probability of success. Assumptions at the start of development can change greatly during that period, which could be as long as 10 years or even longer. For example, advances in science may change biology hypotheses, the number of patients, the status of competitive products under development, and social circumstances. There can be a variety of changes here. There is a high degree of uncertainties while huge investments are required. We can say it's a business that requires very difficult decisions about where and when to invest.

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Since the innovative drug development we are working on is highly uncertain,
it is necessary to support optimal management decisions based on simulation,
in addition to "prediction from past data", which has been remarkably developed by AI in recent years.

| | **Conventional** | **Current**<br>**Focus Area Approach** |
|---|---|---|
| **Available data** | • Much data accumulated in-house<br>• Many public databases<br>• Many bibliographic references | • Limited in-house data<br>• Limited public databases<br>• Limited bibliographic references<br>• Rare diseases |
| **Analysis method** | Prediction from historical data<br>(Data-driven) | Prediction from historical data (Data-driven)<br>**+ Inference based on simulation** |

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As was mentioned, in our Focus Area Approach, we use cutting-edge biology and modality technology combinations to create innovative medicines for diseases with high unmet medical needs. Taking this kind of approach means challenging the areas where conventional experience and knowledge cannot be directly applied.

In the conventional business model, it was possible to utilize past experiences and insights to a certain degree. Predictions from historical data, which has developed substantially with AI in recent years, could be difficult in many cases. In the decision-making process was Astellas' Focus Area strategy. Therefore, approach to analytics could be very different from the traditional approach.

First, based on available data, information, non-theories and findings, we built relevant hypotheses as much as possible. These are the hypotheses about the probability of successful project: time required for development, market needs, et cetera.

Next, based on those hypotheses, we design many possible future scenarios for risks, opportunities, the development status of competitive products, et cetera. We describe these scenarios mathematically and simulate them so that we can find ways to improve Astellas' VALUE we create. In other words, we use a data-driven approach to investigate causes from the results for real or data and information and repeat forecasting based on simulations of the hypotheses we built in order to provide outcomes and scenarios that inform and support strategic decision-making.

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**Important Points for Simulation**
- Forecasting by "range" rather than "single points"
- Identification of scenarios and countermeasures
- Accumulation of data to update assumptions and countermeasures
- Modeling to control uncertain situations

**Benefits of Simulation**
- Decision-making based on trade-offs
- Transparency and consistency in decision making
- Updating of actions in response to changes in the internal and external environment

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An important point in modeling and simulation business structures is to express the impact of possible events not as a single point, but as values with a range. By expressing in ranges, we can generate a variety of scenarios and identify measures to be taken in accordance with scenarios. The ability to envision diverse scenarios and prepare for action are essential when dealing with future uncertainties needless to say.

As an additional area, we stimulate the virtual execution of each action and quantify the risks and benefits. This approach can bring about three possible benefits. First, we can consider the risk/benefit trade-off and then propose optimal action. The second advantage is that decisions can be made with a higher degree of transparency and objectivity compared to decision-making purely based on human experiences and intuition. The third benefit is that we can update our measures in response to changes in the internal and external environments. It is possible to provide decision makers with appropriate information on a real-time basis.

Some of these points may be difficult to understand, so I will take up the COVID-19 as an example to explain.

It was an unknown infectious disease with no epidemiological data, but countries had to make various decisions. Initially, with little data available, decision makers still need it, so various experts created models to predict the spread of infection and the impact of measures to be taken.

They started with simple macro models and kept developing them so that they could make a decision to respect people's behavior or keeping down the infection as much as possible. As the actual situation of the infections became clearer over time, the accumulation of the model improved with data accumulation and we could implement more appropriate measures.

In this way, it is useful to utilize data analysis and simulation in a well-balanced manner. The pharmaceutical industry is a high-risk, high-return business with high uncertainties. Our analytics do not just show what we know from the past data but also go even further to consider what actions we should take in the future to create a big VALUE for the Company.

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Over the next few slides, I will show you some concrete examples. I will explain how analyses that deal with future uncertainties are being used in a variety of situations from individual project planning to overall company portfolio management, to progress management against performance goals.



Simulation of Project Valuation in Drug Development
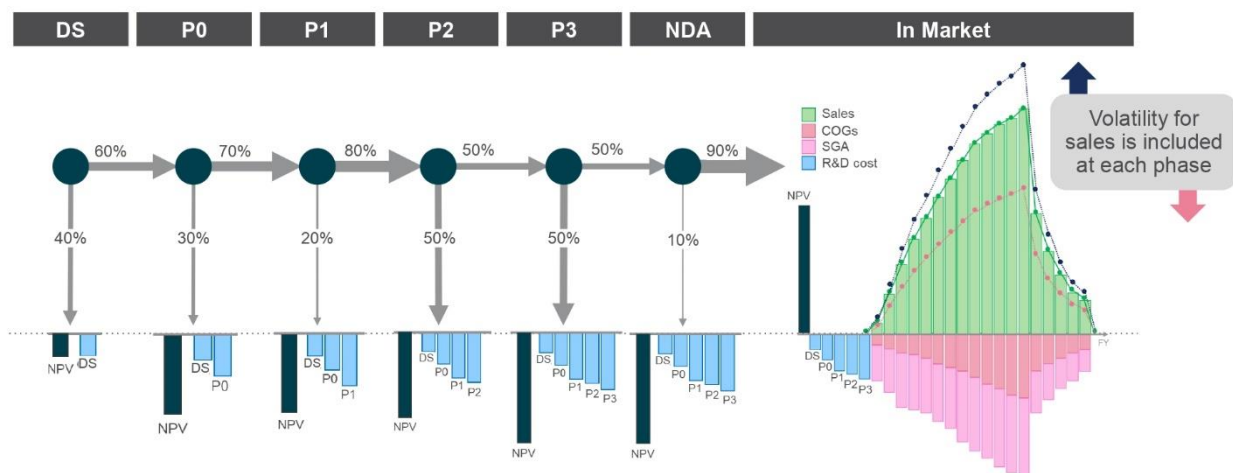
*Numbers are examples

DS: Discovery stage, P0～3: Phases of Clinical Trials, NDA: New Drug Application, NPV: Net Present Value

This page shows an example of using simulation to calculate the VALUE of an individual project.

Project VALUE calculation plays an extremely important role in go, no-go decision project and due diligence for in-licensing. It is essential for proper allocation of resources for strategy execution. Just like Kamoto mentioned a little while ago, the traditional NPV method using discounted cash flow risk adjustment does not account for financial uncertainties. This makes sales forecasts a single-point estimation. As computing processing power has improved, it has become possible to execute tens of thousands of simulation experiments at high speed. By turning project VALUE estimates from a single point to VALUE range, future risks can be evaluated quantitatively.

As mentioned previously, new drug development takes a long time, uncertainties and factors that contribute to the VALUE of the project, such as the probability of success and revenue prospects, vary greatly depending on the project stage.

For example, projects in early stage of development have large fluctuations up and down, or, in other words, volatility. In the new COVID-19 example that I mentioned earlier, there is a period when the infection has not yet started, there was a similar pattern of fluctuations in this numerical focus when considering how much the infection was spread and how severe it'll be. This simulation also expressed the magnitude of certainty during this period of fluctuations.

For example, on this slide, on the right side, the red is a lower fluctuation and blue indicates the upper fluctuation. As you see on the slide, project VALUE evaluation, you have to consider a lot of factors such as R&D costs to success, COGs, and such and such. Simulations can quantify how much these variables affect the calculated VALUE. This is called as a sensitivity analysis.

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Simultaneously considering the uncertainties of all factors is most impossible if it has to be done manually, but simulation makes this impossible possible. We believe that using advanced simulations to increase the accuracy of VALUE calculations that contribute to strategic investment through advanced simulations will have an impact measured in tens of billions of yen.
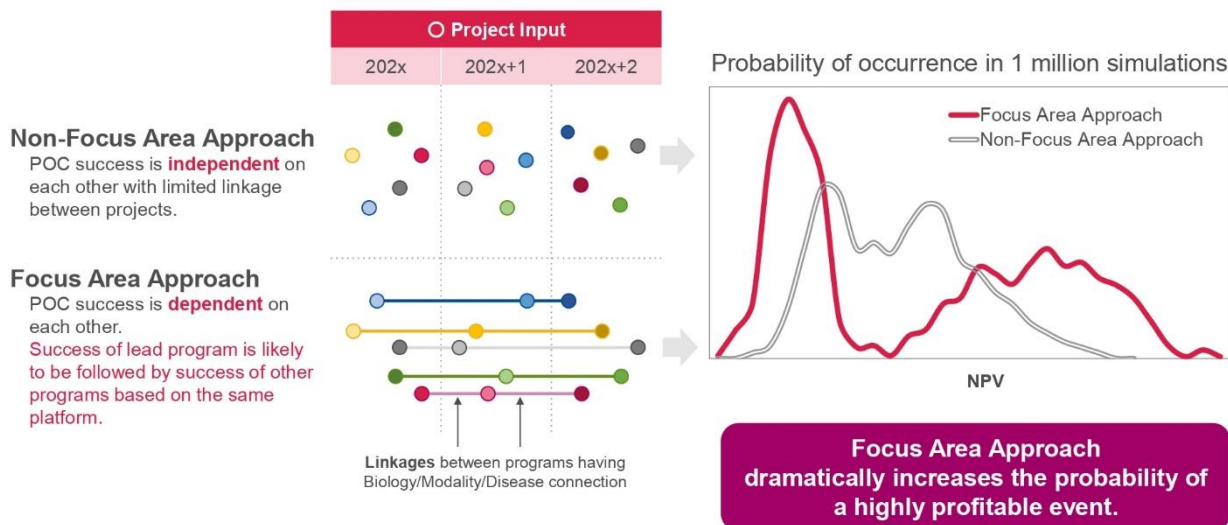


On the previous slide, we evaluated the business VALUE of single project using simulation. On this slide, we are evaluating the VALUE of a multi-project portfolio.

Through portfolio simulation, we're able to prioritize projects and also, we can determine the appropriate portfolio balance for the Company. This slide is an example of using simulation to quantify the effect of the key feature of the Focus Area Approach that brings the continuous stream of new drugs, not one-off project.

We compared the result of models where the continuous stream of new drugs was used to increase the correlation between projects. For example, the portfolio is designed so that if the lead project achieves the PoC, then the subsequent project can also achieve PoC, the FA Approach against models where there was a limited correlation between projects and portfolio, the non-FA Approach.

In doing so, we found when FA Approach-based portfolios were compared to non-FA Approach portfolios, the probability for the occurrence of a high-profit event was dramatically increased. As you see it in this simulation analysis on the right graph, toward the right, then portfolio VALUE goes up. So in this red again, the probability of gaining a bigger profit is likely to be increased. We believe these results validate the FA Approach.

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## Simulation-based forecasting and decision-making

Utilizing a model based on Monte Carlo simulations*, factors such as development success/failure and sales ups and downs are taken into account.
→Obtain possible scenarios and their probabilities of realization for pipeline outcomes

**1** Generate 10,000 random observations **2** Calculated cashflows for each project **3** Output NPV Distribution

**Observation 1 | Baseline**

| | | | | | |
|---|---|---|---|---|---|
| Platform A | ● | ○ | ○ | ○ | ● |
| Platform B | ○ | ○ | ● | ○ | ○ |
| Platform C | ○ | ● | ○ | ● | ● |

**Strategy A | Two failures allowed**

| | | | | | |
|---|---|---|---|---|---|
| Platform A | ● | ○ | ○ | ⊗ | ⊗ |
| Platform B | ○ | ○ | ⊗ | ⊗ | ⊗ |
| Platform C | ○ | ● | ○ | ⊗ | ⊗ |

**Strategy B | Three failures allowed**

| | | | | | |
|---|---|---|---|---|---|
| Platform A | ● | ○ | ○ | ○ | ⊗ |
| Platform B | ○ | ○ | ● | ○ | ⊗ |
| Platform C | ○ | ● | ○ | ● | ● |

● Launch ○ Fail ⊗ Not Done
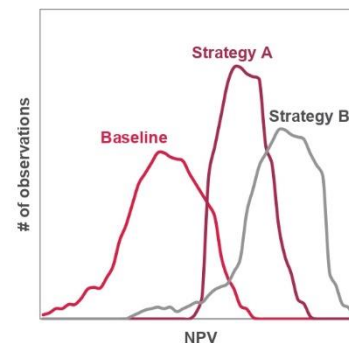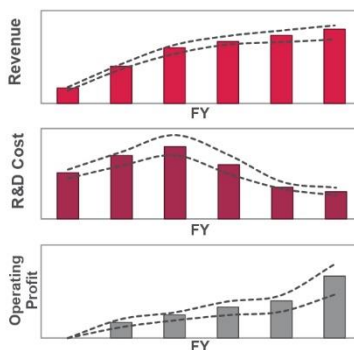
*Monte Carlo simulation: A stochastic model that allows an element of uncertainty to be incorporated into future forecasts. The model can be used to produce different results each time based on the occurrence or non-occurrence of the uncertainty factor and the amplitude of its impact.
NPV: Net Present Value

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Here is an example of how simulation can be used for midterm goal setting and also performance management. We simulate the variation in sales for the entire Company including both launched products and the programs in our pipeline.

As mentioned earlier, project progress is affected by many uncertainties such as the result of clinical trials and activities of other companies. Early-stage projects are particularly subject to great uncertainties, so deviations from assumptions often occur.

If the simulation results indicate a high possibility of deviation from their target, we are able to pretest intervention strategies by identifying measures to fill the gap, rerunning the simulation, evaluating the risks and the benefits of the measures, and determining the optimal plan.

The focus of this long-term company-wide strategy investment planning is to plan the measures required to increase corporate value rather than improving the accuracy of forecasting sales.

When confronting business issues from medium- and long-term perspectives, it is quite useful to make use of the assumption [run to] simulation on top of the data-driven approach. AI models like Open AI, GPT4, data-driven technologies that are trained with a huge number of parameters from a huge amount of data.

In contrast, strategic decision-making and management requires solving complex trade-off problems involving future investments and multiple factors with limited data. In our example, we used a hypothesis-oriented technique to create scenarios and make a deductive guess.

Data-driven AI is of interest to every industry, but Astellas is promoting management DX that utilizes both data-driven and hypothesis-oriented models, which we believe is competitive advantage.

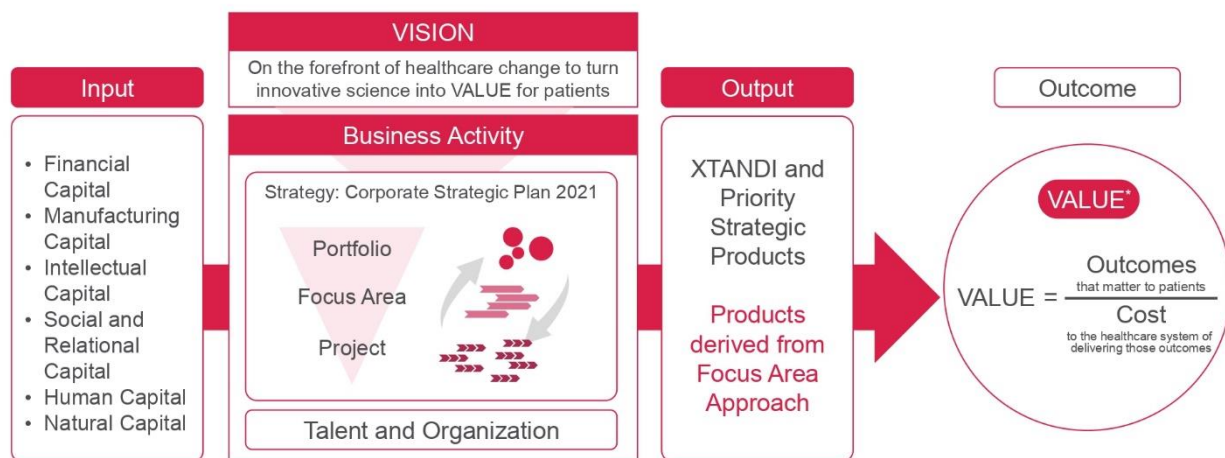So far, I have explained in detail the use of analytics for the Focus Area Approach, which is the core of Astellas' business activities. From here, I will introduce examples of specific initiatives.

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

Here with the diagram that Okamura showed at the beginning, but it now shows the overall picture of how Astellas creates VALUE. At Astellas, we use analytics in every area of this VALUE creation to maximize VALUE.

Here are some of the initiatives that AIA is involved in. Each box represents a crossover area of Astellas' VALUE creation. The initiative in the upper-right calculates VALUE based on the real-world data and selecting optimal indications determines which indication or indications will yield the highest VALUE for product.

Similarly, insights of innovative organizational structure through utilization and analysis of human resources data, in the lower left, is an initiative connecting the input of human capital, on the left, with the human resources and organization at the core of business activities. By improving utilization of this input with the power of analytics, we expect that the final VALUE will increase.

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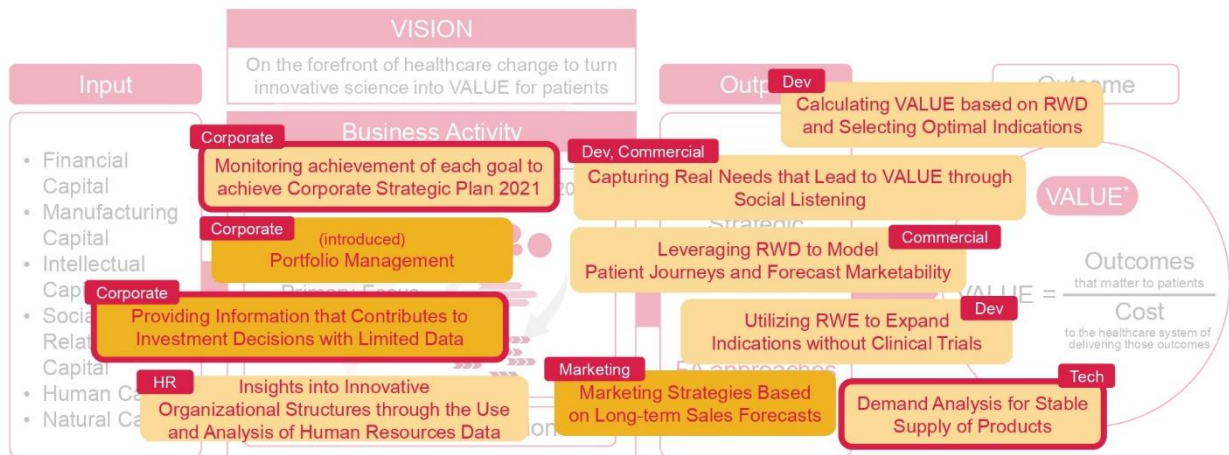SCRIPTS
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14

Analytics is Utilized in All Areas of Enterprise to Maximize VALUE

Data-driven + Simulation

18

* Initiatives not introduced during the presentation are also listed in the Appendix.

VISION
On the forefront of healthcare change to turn innovative science into VALUE for patients

Input
- Financial Capital
- Manufacturing Capital
- Intellectual Capital
- Social Relational Capital
- Human Capital
- Natural Capital

Business Activity

Corporate
Monitoring achievement of each goal to achieve Corporate Strategic Plan 2021

Corporate
(introduced)
Portfolio Management

Corporate
Providing Information that Contributes to Investment Decisions with Limited Data

HR
Insights into Innovative Organizational Structures through the Use and Analysis of Human Resources Data

Dev
Calculating VALUE based on RWD and Selecting Optimal Indications

Dev, Commercial
Capturing Real Needs that Lead to VALUE through Social Listening

Leveraging RWD to Model Patient Journeys and Forecast Marketability

Commercial

Utilizing RWE to Expand Indications without Clinical Trials

Dev

Marketing
Marketing Strategies Based on Long-term Sales Forecasts

Tech
Demand Analysis for Stable Supply of Products

VALUE*

Outcomes
that matter to patients

VALUE = Outcomes / Cost
to the healthcare system of delivering those outcomes

*Adapted from "What Is Value in HealthCare?" Porter, M.E. (2010). New England Journal of Medicine
HR: Human Resource, Dev: Development, RWD: Real World Data, RWE: Real World Evidence

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And the box orange color and color intensity shows if data-driven approach is utilized or on top of the data-driven simulation is utilized. This might be a repetition, but Astellas utilized both data-driven and also assumption-oriented approaches for the management DX so that we can gain the competitive edge.

All are included in this presentation material, but because of the time, we would like to focus on only those with this thicker square and others, but you can refer to the appendix.



Monitoring Achievement of Each Goal to Achieve Corporate Strategic Plan 2021
Data Visualization

19

**Problem**
- To transform into an innovative organization, cross-divisional and ambitious goals (Shared Objectives) are set. Data on initiatives related to goals and their progress are centrally managed, but the volume of information is increasing.
- As the amount of information to be aggregated and checked increases, the time available for sense-making is reduced.

**Solution**
- Developed a dashboard to support management decision-making by automating the analysis and processing of large amounts of data
- Visualization of initiatives and progress, enabling prioritization of critical information and extraction of trends

**Value**
- Time from data entry to visualization reduced from 3 days to 15 minutes.
- Report creation is focused on meaning-making over production.

Verified in FY2021, currently being utilized

Count of Report Updates by Element Family

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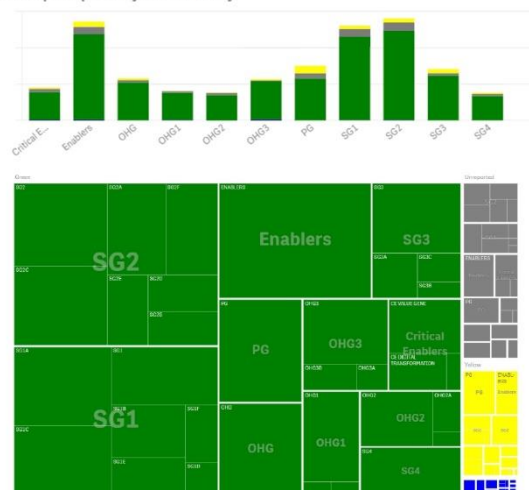
The first one is the simple DX case where data-driven approach is utilized. This is an example of a visualization for project progress management.

Many projects are being implemented to achieve the strategy goal set in the CSP2021. Most of these projects are cross-functional and so require multiple departments to work together. While the information related to each project is centrally managed, the amount of information was so large that it was not possible to understand the progress of each project at a glance. Nor was there any mechanism to address the situation in real time or near real time.

We have developed a dashboard that makes the analysis and processing of huge amounts of data and supports decision-making for management strategies. The progress of project is linked to each logic, goal, and objective, making it possible to prioritize projects and extract trends. As a result, we were able to reduce the time required from data entry to analysis results from three days to 15 minutes.



This is the second case. Demand focusing is a fundamental activity in most industries for ensuring a stable supply of product in supply chain management and the pharmaceutical industry is no different. Model accuracy can be improved by tailoring the prediction model to the target disease and the patient profile of the drugs such as past results with now effects and calendar effects.

In this project, we developed a platform that automatically generates multiple times with focusing models of different types, compares the focusing capabilities of each model and then selects the most appropriate model for each product and market. Increased accuracy in demand focusing is expected to lead to more stable product supply and cost estimation.

Compared to the previous portfolio analysis and midterm plan analysis that contribute to mid to long-term strategy decision-making where solutions was centered on hypothesis-based simulation and modeling techniques. The dashboard and supply chain analysis examples rely on data to understand the issues and solutions. Here, data-driven methods are central to the solution.

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## Providing Information that Contributes to Investment Decisions with Limited Data
### Real-Option Valuation

**Problem**
- Speed is important in asset evaluation, but human evaluation is time-consuming and expensive
- Especially in the early stage, there are many cases where data is insufficient, and the results will differ if different people perform the estimation.
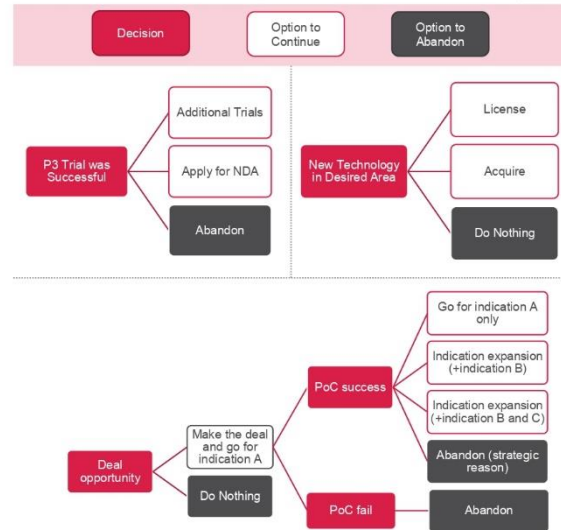
**Solution**
- Developed a Python-based methodology based on an external dataset of tens of thousands of compounds that can be evaluated even in the presence of missing data (e.g., how long and how much does it cost to target a certain indication with a certain compound, how much sales, etc.)

**Value**
- Quick valuation of early-stage assets
- Increased information for early-stage investment decisions

**Currently under verification**

Decision | Option to Continue | Option to Abandon

P3 Trial was Successful → Additional Trials / Apply for NDA / Abandon

New Technology in Desired Area → License / Acquire / Do Nothing

Deal opportunity → Make the deal and go for indication A → PoC success → Go for indication A only / Indication expansion (+indication B) / Indication expansion (+indication B and C) / Abandon (strategic reason)

PoC fail → Abandon

Do Nothing

POC: Proof of Concept, NPV: Net Present Value, P3: Phase 3 clinical trial

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This is the third and the last example. This is a bit different from the previous one. As has been mentioned a little bit, here is a bit more advanced method, it's users. So let me go into a more detailed explanation about how we VALUE the project with a high degree of uncertainty.

As we have said many times before, the progress of early-stage project is subject to great uncertainties. In these uncertain times, flexibility in decision-making itself is of high value. The earlier the project stage, the more room there is for making various decisions such as strategic withdrawal or expansion of indications. So depending on the situations, we can make the flexible decision. In other words, there are many opportunities to maximize the benefits of success while minimizing the cost of VALUE.

Therefore, factoring in the VALUE of flexibility into current VALUE is important for early-stage evaluation. However, traditional calculation methods have not been able to fully appreciate the VALUE of flexibility. Therefore, we are implementing a new method based on the concept of real options.
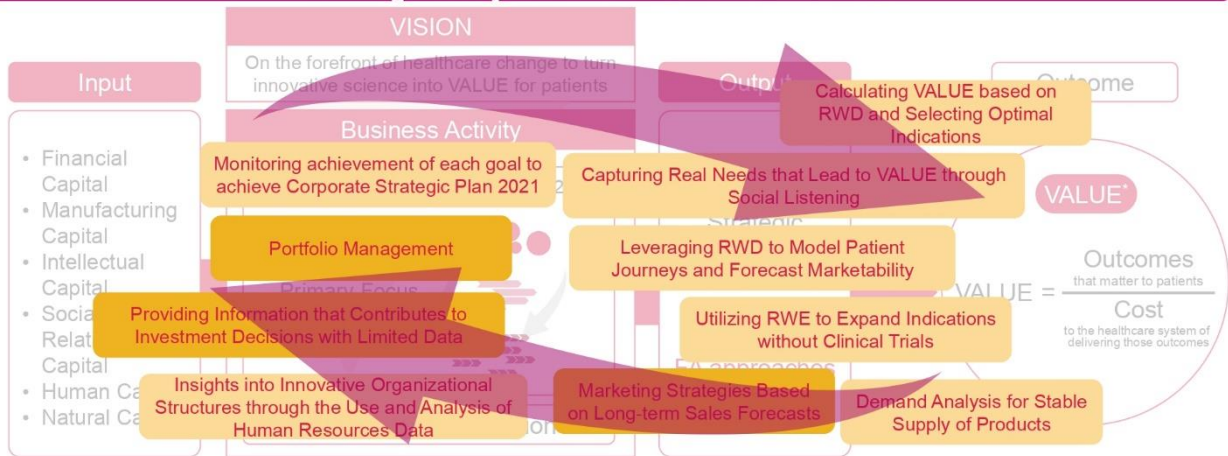
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**What Astellas is Aiming for with Corporate-wide Digital Transformation**
From point solutions to end-to-end

**A state in which all data, from management decisions to individual projects, are organically connected to maximize VALUE**

VISION
On the forefront of healthcare change to turn innovative science into VALUE for patients

Input
- Financial Capital
- Manufacturing Capital
- Intellectual Capital
- Social Relation Capital
- Human Capital
- Natural Capital

Business Activity

Monitoring achievement of each goal to achieve Corporate Strategic Plan 2021

Portfolio Management

Providing Information that Contributes to Investment Decisions with Limited Data

Insights into Innovative Organizational Structures through the Use and Analysis of Human Resources Data

Calculating VALUE based on RWD and Selecting Optimal Indications

Capturing Real Needs that Lead to VALUE through Social Listening

Leveraging RWD to Model Patient Journeys and Forecast Marketability

Utilizing RWE to Expand Indications without Clinical Trials

Marketing Strategies Based on Long-term Sales Forecasts

Demand Analysis for Stable Supply of Products

Output          Outcome

VALUE*

$$VALUE = \frac{Outcomes\ that\ matter\ to\ patients}{Cost\ to\ the\ healthcare\ system\ of\ delivering\ those\ outcomes}$$

*Adapted from "What Is Value in HealthCare?" Porter, M.E. (2010). New England Journal of Medicine
HR: Human Resource, Dev: Development, RWD: Real World Data, RWE: Real World Evidence

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The reason I said based on is that while real options themselves, concept is derived from financial engineering. We do not directly incorporate them into the VALUE calculations of early-stage pharmaceuticals. We utilize the hypothesis-oriented simulation approach so that we can make the advanced option evaluation. We have also optimized the programming to calculate the VALUE quickly. As a result, it can be used in situations where a quicker turnaround for VALUE calculation is required such as evaluating the introduction of external assets.

These are some examples of specific initiatives, which I introduced today. This might be the repetition, but we make use of the data-driven as well as the hypothesis-oriented simulation approach for management DX and we believe that this is going to be the competitive analytics capability for us.

As Okamura mentioned in the very beginning, Astellas' goal for data analytics is to maximize VALUE by organically connecting all kinds of data from management decisions to individual projects. The use cases that are introduced are point solutions. In other words, these analytics provide partial solutions when viewing the VALUE creation chain as a whole.

In the future, we aim for the complete end-to-end analysis VALUE creation chain to organically connect all data and create great VALUE in the most efficient manner.

This is all for me. Thank you very much for your attention.

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# Question & Answer

**MC:** Thank you very much. We now would like to take questions from the audience. In this Q&A session, we will do questions related to this explanatory meeting. If there are multiple questions which are similar to each other, we may group them together. Thank you for your understanding.

We have the first question.

**Ikeda [Q]:** How analytics can contribute to the VALUE defined by Astellas, please explain once again.

**Ito [A]:** Thank you for your question. As was mentioned in today's presentation, the VALUE defined by Astellas was explained today, capital VALUE. Also outcomes that matter to the patient, divided by cost to the health care system, there are variety of value chain in the pharmaceutical industry, experts in their respective field are working very hard. We have lots of data in the individual areas, so using a data-driven approach to start with DX in the field.

And then, as we talked about today, for management decisions, we have to make management decisions and there are a lot of uncertainties. Even if we don't have a lot of data, we have to look into the future, like 10 years' time from now, to make major decisions like investment decisions.

In line with the data-driven approach, we have to consider scenarios and also to evaluate to address the uncertainties using a risk-based approach. By working on all of these, we can contribute to the VALUE and organically, if this is going to be connected organically, we can create more synergy to maximize the VALUE, in my view

**Okamura [A]:** Me? Okay. In principle, the VALUE is with a numeric and denominator. Whether we can minimize the denominator and maximize the numerator, the numerator is outcome, but actually, a lot of elements, diverse elements are included in the numerator because of the drugs.

Whether it's going to be effective or not, efficacy is important. Effectiveness, efficacy may be great, but patients may have to stay in hospital then, Or the efficacy may not be so great, but patients can be taken care of at home, which is better. This is a very complicated issue. And just looking at the near sales studies or simple parameters to calculate this, you can come up with an asker quickly, but you may make a wrong decision. Very complicated systems could be introduced here, but it will take time and the results will be complicated. You have the results, and you don't know how to interpret the results. And what can serve as bridges are the analytics.

We have the data in the world. Instead of just making decisions based on the data available in the world, you build hypothesis. And if that happens with a certain probability, what could happen, that can be shown to us proactively in advance. We use simulation technologies like that, then we might have missed big opportunities, but we may be able to bet on them.

We may have our own understanding and something great could happen, but there can be pitfall of just a few percentage probability and company may not be able to go anywhere. There can be such a risk. We would build very complicated systems, but the results can be shown to us in an easy-to-understand way. This is like a crystal ball in my view.

**Ikeda [M]:** Thank you. Next question.

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**Ikeda [Q]:** In FY2023, AIA division and information system divisions are planned to be integrated. What's the background of this? Or what kind of synergy would you expect thanks to this integration?

**Okamura [A]:** Let me answer. Well, under the management strategy, there is the information system division as well as advanced informatics & analytics division. So those are hanging there, just like the brothers. And in the beginning of Ito's presentation, he mentioned that there are three divisions, AIA information system, as well as Rx+. Rx+ is following something different, a different business, so let me put it aside. But AIA and information systems, well, each strength and each roles have been existing, that is so true. However, because we thought that it is better to have these two integrated so that we can share the skills and also we can share the information. Well, sometimes each division have the overlapping of the things that they are doing or they not practice enough to do the activities because of the separate existence of these two different divisions. So with integrating these two, we believe that we can change the situation.

I'm not a specialist of the digital itself. So the management strategies, if they can handle these two in a very flexible manner, but so far, it was not really so. And currently, we consider it is more effective if there is the one contact or the window, which can cover these two functions. From this perspective, we decided to integrate these two.

That's all for me.

**Ikeda [M]:** Thank you. We'd like to move on to the next question.

**Ikeda [Q]:** Investments into AIA. To what degree you are investing into AIA? Initiatives are mainly internal initiatives by Astellas? Or are you promoting collaboration with other IT companies as well? This is the first question as far as you can answer.

**Okamura [A]:** I don't have specific figures at hand, so maybe you can contact the corporate advocacy and relations later. Quite a huge amount of money is being invested. We are confident about it. We have data scientists. Securing necessary number of data scientists requires a huge amount of money. Considering the human resources and financial investments, we are investing a lot. Specifically, internal initiatives or a collaboration with outside companies, Ito-san can respond both.

**Ito [A]:** We have joint research with outside partners. And also, depending on the Group or tower, it's different, but we have internal initiatives. Business challenges we have are being resolved by many initiatives. AIA itself belongs to corporate and we have been collaborating with various sections within the Company. In our work, external capabilities could be leveraged in some cases. But in principle, we have internal businesspeople. We collaborate so that we resolve business challenges in many cases.

**Ikeda [M]:** Thank you very much. From the same person, there is the second question.

**Ikeda [Q]:** Analytics can generate the competitive edge. To identify with limited data, information must be provided about investments decisions like real option valuation. For early-stage candidate products and in-licensing products, your insight will be greatly improved. Is this an initiative leading to the competitive edge in identifying these areas compared to other mega pharmas?

**Okamura [A]:** Let me respond. Well, we analyze our capabilities. To identify a great project would be enhanced, but rather, of course, for me, the accuracy and the quality of decision-making can be enhanced. That's my belief. But as I said before, early-stage products, the long time into the future with lots of uncertainties, so in the case of real option, future uncertainties and the flexibility of decision-making must be incorporated into the current valuation.

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And looking at the actual compounds and technologies, we can approach the actual VALUE to make the more accurate evaluation. In that sense, our insight or the ability to identify great things, so that we can invest and the quality can be enhanced as well as the VALUE.

There are other things. It's not just about option and evaluation but scenario analysis would enhance the VALUE, but if I may add. Just enhancing the accuracy of prediction is not enough. Considering the future uncertainties, we can optimize the action we can take right now. That's our focus. Just increasing the accuracy of the forecast is not the final objective in the end.

How I should explain, I don't know. To begin with, when you say our capabilities to identify whether it's good or bad, if we know that, decision-making can be easy because you can just select what's great. But rather, we may think something is very good and as we proceed, it may not be so good. Initially, you may think it's not so great, but with a certain trigger, it may turn into something great. That's why in drugs, it's very difficult. That's the premise.

What did we do before? Based on these assumptions, we calculate the cash flow and we multiply the probability of success. The NPV after probability adjustment is going to be JPY200 million positive. If we just hear about it, we say we'd go for it. But if the NPV is the same JPY300 million, the probability of success is higher cash flow would be generated earlier, but it can be very thin in our nature.

Or it may take a long time to develop and the probability of success may be very low. But once it's going to be successful, it can generate huge amounts of revenue. And the result could be the same JPY300 million after discount. So which are you going to choose when it's the same JPY300 million, we cannot really select just based on this information. Our capabilities and the product portfolio must be looked at closely, which is the JPY300 million we require right now. We take this JPY300 million, but in case of a certain event, we would stop it and shift to something else. Such complicated decision-making must be made possible. To do so, point forecasting and the probability of success, we did not change and mechanical calculation of numbers, we shouldn't look at it. What kind of situation will impact us into the future, it must be visualized. Otherwise, it's not going to be useful for us to make decisions.

As Ito showed, there is a range somewhat. And with certain priorities, it may show which is more important for us right now, until when we should continue investments, and at what timing we should make the final decision to maximize the overall return. It's a very complicated decision-making process. And in order to contribute to the discussions, as a premise, a lot of information has been provided to us.

**Ikeda [M]:** Thank you very much. Next, that's going to be a question here too about the size of the investment.

**Ikeda [Q]:** It's about the question regarding the number of the employees. AIA division, system information division, actually, how many employees are belonging to these two divisions? It might be difficult to come up with a number. However, what would be relatively the size?

**Okamura [A]:** Well, I don't have the number in my hands here, but AIA, a little less than 100. I think that is about the size. And information systems division, I don't have, sorry, the number. I think the number of the employees is bigger than AIA.

**Ito [A]:** Right.

**Okamura [A]:** Probably, it's about the size in the ratio of 1:2. To what extent if we can just disclose the number, I don't know.

**Ito [A]:** Right. It might be difficult to answer the specific numbers, but I think that's about the sum.

**Ikeda [M]:** And that is the question from the same person.

**Ikeda [Q]:** What is the frequency of the analytics correction for each portfolio? What will be the timing? What will be the frequency for that?

**Okamura [A]:** Well, in the past, we didn't do the correction action so frequently. But currently, quarterly-wise, the model is updated. So that's the process we've introduced. For that purpose, as much as possible in the real-time basis, portfolio management will be introduced, and we've already started that project about a couple of years ago. And it's been quite utilized. So financial analysis update, frequency is now increased, I believe.

Well, for example, the materials for the shareholders' meeting, the portfolio VALUE is one of the criteria for the yearly bonus for us. The number cannot be discretionarily changed. That is based upon the very rigorous SP. At a certain timing, certain events are corrected to fix the VALUE. So such rules are meticulously decided. But the data for the project correction at a certain point of time, well, there are some factors in timing as well as externally, like the competitors' situation that has to be taken into consideration. And not necessarily about specific project, but for example, IRA is now introduced officially. In such kind of a site or factor happens, then it's not something we can wait for the quarterly basis of the management. So depending on the situation, we have to be flexible for the correction.

At one hand, we are quite rigorous based upon the rule. And on the other hand, there are areas that evaluation will be changed depending on the events and the factors that happens at a certain point of time.

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

**Ikeda [Q]:** Next about fezolinetant, scenario analysis about fezolinetant. It may be difficult to answer to a certain degree, but please share as much as possible. A team is doing scenario analysis, what kind of cases are being assumed? Bullish case or bearish case included in your assumptions, on what kind of action you're going to take based on each case? As far as you can share, please respond.

**Ikeda [M]:** Are you doing this?

**Okamura [A]:** Yes. But we're trying to do this. This is a very concrete thing, and it's very difficult to respond, so I'd like to give you a somewhat ambiguous answer. But roughly speaking, as we announced the other day, this February, PDUFA (Prescription Drug User Fee Act) date was expected for approval for February this year. That was the assumption for us to develop our plans, but it was extended by three months against our expectations.

Because of the three-month extension, if we take it as is, what would happen? What should be done to catch up with this? Initial year is going to be 12 months or 9 months. It's difficult to catch up. But in the longer term, we should be able to catch up with investments.

If we increase investments, can we catch up or investments may remain the same? The timing of usage of money can be changed to catch up. In the near term, there can be a variety of events which can occur and there can be a variety of actions we can take. We can combine a lot of things to simulate. Then, with this additional amount of investments, it could be acceptable so we can accept that much additional investment to select the scenario to catch up. Or this year, it's very tough, so we cannot make additional investments. So in the longer term, the results could be unsatisfactory to a certain extent, but we can go this far in the current fiscal year.

For example, we are asking for such information right now. It's not going to be meaningful just for decision-making, but when fezolinetant is going to be launched into the market, because of the simulation, we use

assumptions and conditions; whether they are realized or not, it must be monitored and checked. This is going to serve as a guide to monitor and check. We're not just talking about the pie in the sky, but the model we use in this process can be used to verify the trajectory for growth. In that sense, it's a useful tool.

So it's not just the end of the story with one analysis, but it can be used for multiple purposes. So a great model is being built.

**MC [M]:** Thank you very much. It was a difficult question, but thank you for responding. Next question.

**MC [Q]:** Slide 15, that's about 1 million simulations, and there is the probability. I would like to get explanation about that as well. You mentioned the generation probability is overwhelmingly increased with where the large profit can be expected. But on the other hand, if a PoC cannot be gained, then there might be the situation where the other projects also become difficult to make a success. What do you think about it?

**Ito [A]:** That is right. If you look at this, this horizontal NPV to the right, values are high and vertically, it's the probability of occurrence. And to the right, the mountain is higher. You see that happens in the scale compared to the ordinary approach. So this is whether we can identify the VALUE of the occurrence.

But for the left, you see the Focus Area Approach has a higher risk of the loss, big loss. This is a quite natural thing. We see the continuous stream of new drugs. In other words, there is a correlation of the project. In that case, if one thing doesn't make success, and we have multiple investments, then things as a whole would not make success. Yes, so that kind of failure might take place.

**MC [M]:** Thank you very much. Let me move on to the next question.

**MC [Q]:** Regarding the case examples, today, you shared project evaluation examples. The environmental changes due to COVID-19 and the future environment changes in response to the cost analysis and also cost effectiveness analysis for all MRs and the optimal MR structure for the future and the structure analysis for sales and marketing and medical affairs. What about the examples of using this for cost analysis in these cases?

**Ito [A]:** Specific examples of cost analysis in sales and marketing will come from now on. We tried once in some areas. So it varies. But cost analysis in the corporate strategy department, we are discussing right now company-wide, how to allocate resources to optimize. And just looking at the cost would not be enough to enhance the operating profits. We have to look at the benefits and, of course, we have to look at the trade-off. We have to go deeply into that area in your analysis.

Commercial resource allocation, depending on the product and the target items, it can vary. Even if it may be mature, it may be into the market for many years in our business, then we have past data, historical data, and we can use a statistical model.

At the same time, what kind of commercial activities would be done to have certain responsiveness? Based on such data, optimal resource allocation can be considered. There can be such an approach. Like the fezolinetant example, we are going to do it for the future. We don't have a lot of data.

How to allocate resources there? As was mentioned before, various scenarios and also discussions with experts will take place to perform simulations. So there are such activities right now.

**MC [M]:** Thank you very much. Next question.

**MC [Q]:** The chart or the analysis of the range, as has been explained, are utilized for the decision-making, but the decision is made by the executive directors or Board of Directors' meeting, the discussion will take place

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there or external directors would join for the decision-making? In what way decision will be made? Or based upon such a situation, the roles of the external directors will be changed? It would be basically the supervisor as its position, but how would it be changed?

**Okamura [A]:** Thank you very much. Well, in our company, we have the clear demarcation between Board of Directors and also the executive management. Board of Directors are based on the strategic perspective. And for each project, that is discussed and the decision is made within the meeting of executive directors. So the result of the analytics, who would use it for the decision-making? Basically the executive directors, well, Executive Committee, CXO, the members of them will be the decision maker. But for ideal state, the Vice President of a division is expected to make a decision based upon this analysis.

Having said that, the range is limited, but it wouldn't go such high. It has a wider range. So it will be a great thing if you go higher, but it will be a great failure if go quite low down. So depending on the level, we have to make a decision. For example, as executive director level make a decision, but the Board of Directors don't know anything about the decision-making. That is not the situation we would like to avoid. So we need to increase the level of literacy amongst the external directors as well.

But when it comes to the track expertise, decision-making, and discussions, well, to what extent we expect from them for their understanding, well, of course, we want them to understand the essential level for the decision-making in a sufficient manner. So to that level, the literacy is needed to be enhanced. That is the role that we can expect to the external directors.

And also, we would like to have further occasions of communication and in what way the analytics is utilized and that is what we would like to honestly explain to them. Again, we have a Board of Directors' meeting and depending on situations, we select the hot topics. And outside of the Board of Directors' meeting, we have the program to share the information. Ultimately, the VP of the executive level or the team in charge of certain projects will have opportunity to provide the information to them. We have such occasions. It's not really a training, but we have the location so that they can have the discussions. So although the execution and also supervising are separated. However, it's not something that the supervisors are completely being excluded from the execution. So we have a very good balance of the demarcation of the rules.

**MC [M]:** Next question.

**MC [Q]:** The economic benefits to be brought about by DX is the topic of the question. Today, you talked about analytics DX to be utilized for the selection of the VALUE of individual projects. Potential benefit could be as much as billions of yen according to your presentation. As was presented today, the pharmaceutical industry is an industry with high uncertainties. How do you estimate the economic benefits?

As you explained, do you estimate the economic benefit by the combination of the data-driven approach and the hypothesis-driven approaches?

**Ito [A]:** Today, I picked up certain projects like supply chain and dashboard. In those cases, we try to accelerate the speed of decision-making or optimize the cost by taking such approaches. Various industries are discussing DX. By introducing these elements, we can reduce the work process, we can lower the cost which we can calculate, so it's the same. And also, for example, in the clinical development, certain drugs are very mature. In the real-world area, there are already a lot of real-world data. To get additional indications, clinical studies may not be performed by using real-world data too for submission. Is that what we call DX? It's industry-specific, but the clinical costs can be high. If this can be done, we can reduce a huge amount of cost and we can deliver the VALUE to the patients earlier.

Today, particularly in the first half of my presentation, I talked about the strategic decision-making and analytics, which can contribute to that scenario analysis rather than data-driven or controlling uncertainties.

It's a very difficult thing to examine and verify because we are discussing the future like 10 years from now. And we try to see whether our answer was correct or not. We cannot do a lot of projects. It will take a lot of time. After 10 years, we may have answers for just three things or so. And even if you try to verify our answer, it may be difficult to check how much we can estimate.

Regarding the strategic decisions, there are a lot of difficulties. But one thing I'd like to explain. Statistically, this is the discussion of the expected VALUE, which is the basis. For example, if you have [applied] 50% for the top 50% for the bottom, if you get the top JPY100 can be received with one of the two possibilities. If you continue to throw the decline, the end balance is going to be the same. But you can get the expected VALUE in the end. You can get the top. You try to find such a cost, try to enhance the quality of the judgment because of certain costs will have a higher probability of showing the top instead of the bottom.

When we can combine what would show profiling in a clearer way. What should be the combination to maximize the VALUE for the Company must be analyzed, as Okamura mentioned. By using these combinations, there can be a huge amount of expected VALUE we could expect and we can generate.

**MC [M]:** Okamura-san, anything to add?

**Okamura [A]:** I didn't mention JPY10 billion or billions of yen. It's not me. But on page 11, I think, the probability of success, 8%; development period, 10 years; and the cost USD1 billion. Looking at these figures, by changing the probably to success, what is going to be the impact level, you can imagine easily.

As Ito said, it's difficult to check whether our answer was correct or not. In this field, 10 years from now, looking back today, Okamura mentioned JPY10 billion. But you may say 10 years later that you didn't get JPY10 billion. But because of the expectations that we can have that much impact, that's why we do not hesitate to invest a huge amount of money.

I'm applying pressure to Dr. Ito instead of a lot of bills in front of us, this will contribute to the VALUE enhancement for the Company to the future. That's why I'm supporting the team.

**MC [M]:** Thank you. Next question.

## Calculating VALUE based on RWD and Selecting Optimal Indications
### RWD Data Hub

**Problem**

- VALUE of a drug is not only its therapeutic effect, but also its cost of care, quality of life, burden on caregivers, etc.
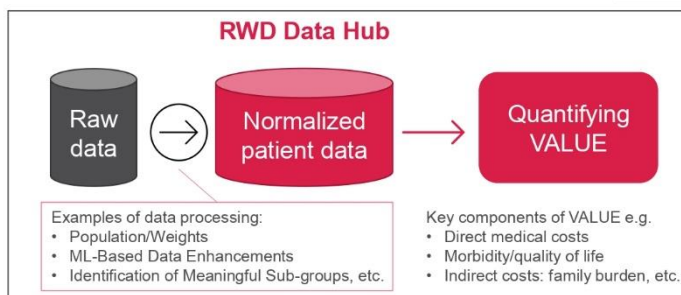- Optimizing VALUE through clinical trials alone is time-consuming and expensive.

**Solution**

Build a uniquely processed data hub based on RWD
- Capable of quantifying VALUE (within 1 day)
- Can perform clinical analysis and evaluation at various stages of the drug development cycle

**Value**

- Faster time-to-market
- Reduction of study costs

**Verified in FY2021 and currently being utilized in multiple projects**

**RWD Data Hub**

Raw data → Normalized patient data → Quantifying VALUE

Examples of data processing:
- Population/Weights
- ML-Based Data Enhancements
- Identification of Meaningful Sub-groups, etc.

Key components of VALUE e.g.
- Direct medical costs
- Morbidity/quality of life
- Indirect costs: family burden, etc.

- National / Global Projections
- Patient Segmentation, Volumes
- Incidence / Prevalence
- Treatment Patterns
- Burden of Disease
- Trial Endpoints
- Health care resource utilization / Cost
- Comorbidities

**Selecting the best indications for maximizing VALUE**

RWD: Real World Data

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**MC [Q]:** So just like Ito-san mentioned a bit, well, you mentioned about the VALUE calculation based upon RWD. It's page 24 of the appendix. So the VALUE calculation based upon real-world data is already utilized for the negotiation of the reimbursement. If so, the result of that analysis is now approved as a consensus with the negotiation counterparty or, for example, payer.

**Ito [A]:** Well, let me answer. In Japan and the United States, the situation is probably different. In the case of the notices, that is, yes, happening. Or rather, I would say that you have to do the analysis based upon the real-world data, otherwise, the VALUE cannot be maintained. That's my understanding.

Therefore, this type of approach is now essential. This is expected to be done. Of course, this is not only about the price of the drugs. This approach is utilized here and there. And this is not only for the purpose of the reimbursement. Of course, reimbursement is aware that it is quite important to utilize this kind of approach. And I think the situation will be different if Japan will go in that way as well.

**MC [M]:** Thank you very much. Next.

**MC [Q]:** Sorry, I don't know enough, but methodologies to utilize simulations into management decisions is being done in one way or another by the pharmaceutical industry? Or is this a unique approach by Astellas? Using simulations in the management decisions, is this a common approach us in the pharma industry? Or is this a unique approach by Astellas?

**Okamura [A]:** When it comes to simulations, it's a broad term to use data to perform simulations. And if this happens next year, what shall we do? For example, forecasting next year, that could be called a type of simulation. At various levels, different companies have their own ways. I'm sure others also incorporating simulations. Otherwise, this is a very volatile world right now. The situation today and continuing to 10 years' time, I don't think nobody is thinking that way in this industry. So what would be the potential risks? If you go this way, what shall we do? If you go that way, what shall we do?

Simulations or some may call this scenario planning, I'm sure they are doing this as well. How objectively you can evaluate this or using data, whether they do this or not and also for one particular event, instead of doing

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this for one particular event, a lot of ongoing things in a complicated way to simulate the entire situation, I think that's the difference, whether they are doing this or not. I think that's the difference.

**MC [M]:** Next question.



Leveraging RWD to Model Patient Journeys and Forecast Marketability
Dynamic Patient Flow Model
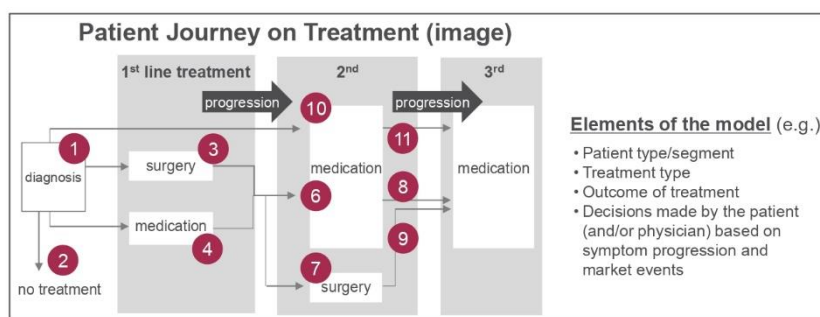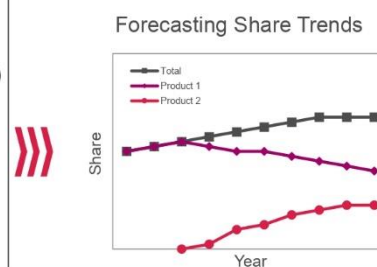
**MC [Q]:** In the presentation today, there was no explanation on this, but refer to appendix slide 27. There is a description about dynamic patient flow model. This is what I'm quite interested in. Would you please briefly explain about this? If the slide can be shown on the screen. Would you please come up with that?

And a related question, this kind of data is utilized for the current sales forecast as well?

**Ito [A]:** Thank you for the question. So here, you see the slide with the previous example. When it comes to, for example, the launch of new products, the sales at that time is what we would like to forecast as much as possible for the appropriate allocation of the commercial resources or coming up with marketing strategies. That is a quite important step to improve the product VALUE.

And this example here that is one new product and how it can be used in the actual clinical setting, that is analyzed based upon real-world data. Having said that, well, I've been saying that this is based upon their real-world data, but that is a new product. The product hasn't been launched yet.

So we have to utilize the information of the similar diseases. What is the current suffer of the patients, what kind of treatment of flow is taking place for the similar diseases? Those are all analyzed.

In the case of the COVID-19, there is this new drug launched in the market and the information flow data is going to be accumulated. Then that situation is run by the model, so the accuracy improves. And we have so much of the information there. Then with the data-driven and times three approach utilized, based upon the past sales data, we can focus the sales in the future.

But just like the case of the fezolinetant a little while ago, for the commercial marketing strategy planning, even before the data is collected in a sufficient manner, we need to start earlier for the consideration. In that case, we would like to make use of the real-world data that is going to be accumulated and we would like to

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also introduce the factor of the simulation so that we can do what-if analysis, many what-if analyses, so being necessary to be conducted.

And the simulation at the time, well, macro, the simple Monte Carlo role for the variable generated, rather than that approach, we consider that each patient is agent to consider about the behavior. So such kind of a micro level of the simulation is also possible. That is something we would like to do.



## Marketing Strategies Based on Long-term Sales Forecasts
### Long-Range Forecasting

**Problem**
- Long-term sales forecasting is uncertain and difficult because of the impact of multiple uncontrollable factors, such as government price controls and increasing market share of competing products. On the other hand, using only a single point estimate based on a variety of assumptions

**Solution**
1. Assumptions are made about the impact and probability of occurrence of each of the factors affecting sales. Monte Carlo simulations generate a "range" of numerous possibilities and outcomes
2. Predicts future trends based on time-series data, using models that leverage statistics, machine learning, and deep learning

**Value**
- Marketing strategies with appropriate estimates of risk
- Improved understanding of possible scenarios
- Ability to pre-test the impact mitigation strategies

**Verified in FY2021, currently being used in multiple projects**

NPV: Net Present Value

**1. Monte-Carlo Simulation**

$$NPV = f_{NPV}(X_A, X_B, X_C)$$

**2. Time Series Forecasting**

— Sales (Predicted) — Sales (Actual)

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**MC [M]:** Thank you. A similar question about slide 26.

**MC [Q]:** There is a slide on long-term sales forecast. Could you briefly explain this page? And to what degree the accuracy of the forecast can be enhanced by this?

**Ito [A]:** As you can see on the slide, we make long-term sales forecast to be leverage for marketing strategy in this example. The two major ways, as has been mentioned many times before, if you haven't accumulated a lot of data, we build hypothesis to use Monte Carlo simulation methodology: the government price control; or reimbursement situation; or competitive situation; and share expansion, it can be a lot of impact from these events. So such impact could be evaluated to make a forecast.

Of course, this has been done from before. But whether the events can actually occur or not, and the volume of the impact was a point estimation in many cases, as I explained initially, we should capture this in a range to quantify the uncertainties, to ensure better risk management. That's about the simulation.

And if you have a certain amount of data, for products, we would use a time series forecasting, sufficient time has passed after launch. There aren't many events to effect, then we use a certain approach for these products. Appropriate analytics approaches for issues would be utilized and applied. What is the precision or the accuracy of the forecast, if a sufficient amount of data is accumulated using advanced statistical methods? Then the precision and the accuracy of forecast has been enhanced in many cases. Using the simulation, it's yet to come. As I explained before, it's very difficult to verify. What's important is the model we built, depending on the update of the information we have to update them to enhance the accuracy and the precision.

**MC [M]:** Thank you very much. Next question.

**MC [Q]:** As AIA division, what would you like to achieve? Or what is the strength of AIA division for Astellas Pharma? What would you like to achieve with the strength of Astellas' AIA?

**Ito [A]:** Well, the pharmaceutical companies, for example, the drug discovery, the analytics is utilized by the specialist there for the drug discovery. And in the clinical trials, the specialists for the clinical trial analysis, when it comes to commercial, there is a specialist for the marketing analysis. In that perspective, I think we are no different.

AIA, that belongs to the corporate and they collaborate with the parts in the different divisions so that we can come up with the VALUE. Of course, there are some challenges. The collaboration is not necessarily always smooth to make a success. But we have experience of five and six years and the issues themselves are already identified. We've already identified the solutions for those issues.

And also AIA data scientists, well, they are data scientists. But it's not that they all do the machine learning or in front of the PC. They have the focus of the certain business domain, and they have their own, each different capabilities. The appropriate person is allocated to the appropriate projects to do this type of analysis. I think that is probably Astellas' unique approach.

Well, if I would say that I want to realize this, that might be really dream like some things, but the members who belong to this department actually realize them. That is a wonderful thing.

When it comes to the specific challenges and the issues, well, with that, you can have a clear emotion. It is relatively easier to realize that. And from time to time, I asked the very difficult things. I ask a lot of difficult things ask to them, but they always make their best effort to come up with a certain outcome, that's why I really would like to support AIA.

**MC [M]:** Thank you very much. This can be the last question.

**MC [Q]:** Okamura-san, Ito-san, I have a question to you. Analytics DX, what is the biggest challenge you think right now? And also, what is the technology which must be supplemented or technologies which are still missing in the DX you are aiming for?

**Okamura [A]:** Compared to before, computing power has been substantially improved compared to before. And the variety of data, setting aside their accuracy, there may be some variability from country to country, but it's now possible to obtain data to a certain degree. The so-called data scientists do exist in a certain number, so if you say, can we do this, it has been realized to a certain degree. So I'm not so worried here.

But the results we generate must be interpreted and discussed. Such literacy, as I have been saying from the beginning, that's the biggest challenge because discounted net present value with a probability adjustment, still it's difficult. If it's integrated into just one number as a point estimation, it's very difficult to go away from that simplicity and easiness. It will take time and everybody cannot come to the same level overnight. So from very sensitive people, we'd like to spread it gradually over time. And easy-to-understand examples can be utilized well to disseminate and educate. That is going to be necessary to enhance the awareness.

Technology-wise, I'm not so worried. But there would be a new series into the future. They can incorporate then one after another. But the literacy, for those who receive this, it's going to be the biggest challenge for us in my view.

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**Ito [A]:** My answer is going to be something very similar. The democratization of data scientists is often talked about the entire employees of the Company, analytics and data literacy and analysis literacy must be retained by them, that's important.

On the other hand, the specialist groups data scientists must communicate are easy to understand to those who don't have such expertise. Storing capabilities is very important. If there is an answer, if they talk about something different in a difficult-to-understand way, nobody would be able to understand. So this is going to be necessary.

If I may add. As I said in the clinical development, clinical study analysis specialists do exist. For drug discovery, we have drug discovery focused people. When it comes to real-world data, which we talked about a few times, we have a lot of real-world data in the world in the health care environment. That's the observation of studies. With secondary usage, there are professionals. And the clinical development people are the experts in the experiments. Different analytic capabilities do exist within the Company.

As was mentioned, computer capabilities have been enhanced, such capabilities to analyze the pharma business already sufficient. Easy-to-understand way to explain on how to use this in the decision-making process, whether we can collaborate among different divisions and departments, I think those are the challenges we have.

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

Well, it's the time. So with this, we would like to close the Q&A session. There are some questions we were not able to answer. If you have any additional questions, please contact the person in charge in the Company.

With this, we would like to close today's webinar. Everybody, thank you very much for your attendance. Thank you you so much.

[END]

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