

# Presentation

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**Matsui:** Hello, everyone. I am Matsui.

Now then, at this briefing on the 29th mid-term management plan, I would like to say a few words by way of opening remarks.

My career history is briefly shown here. I joined TOA Medical Electronics at the time, now Sysmex, in 1985. This year marks my 41st year. During that time, I spent 11 years on overseas assignments. As you can see from my career history, I have been in the sales division almost throughout, and as something I value, I have listed the principles of the three actuals, a management principle that emphasizes going to the actual place (Genba), seeing the actual thing (Genbutsu), and understanding the actual facts (Genjitsu) to make decisions based on reality.)

From the standpoint that working close to customers and the market allows us to gain various insights and suggestions, I would like to continue valuing this principle of the three actuals, especially valuing contact with customers, going forward as well.

## Our Desired Future State



**Together for a better healthcare journey**

Systemex is deeply committed to its supporting role as provider of each individual lifetime “healthcare journey,” utilizing its proprietary technology and solutions in better and better ways.

Systemex will also continue to innovate in testing and diagnosis as important functions within the healthcare journey, collaboratively creating unique values in the areas of personalized medicine and novel treatments.

We will continue to grow as a sustainable company creating social and economic value, providing a greater sense of security among people and the society in which they live.

I would like to look back once again at “our desired future state.”

This is the message we created when we formulated the 2023 long-term management plan. It is “together for a better healthcare journey.” We defined Sysmex's business domain quite broadly, extending from testing and diagnosis to personalized medicine and even treatment.

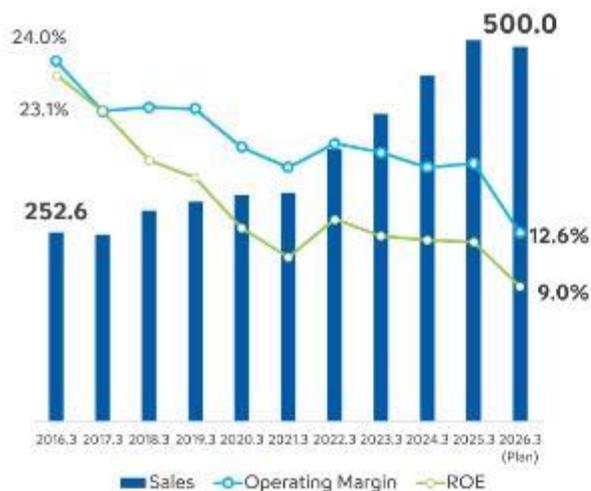
In doing so, it is necessary both to expand our business domain and to dig deeper into and further deepen certain business domains. I believe it is important for us to advance this expansion and deepening in a balanced manner, while taking into account changes in the internal and external environment, the capabilities we possess, and the timing.

Now, when we consider what Sysmex should achieve, I believe it is, after all, deepening. I believe that what is being asked of us now is to dig deeper into the testing and diagnosis domain and take it to the highest level.

## Our Business Performance



■ Performance trends over the past 10 years  
(Billions of yen)



### External

- Robust growth in global healthcare demand
- The Chinese market is entering an optimization phase, with a temporary contraction
- Pressure on sales unit prices due to increased competition

### Internal

- Realizing growth through high customer support and brand power
- Delay in monetization of new businesses and decreased profitability and efficiency due to an increased SG&A expenses ratio driven by DX investments and other factors.

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I would like to review Sysmex's current business performance here once again.

Our sales have grown steadily. I believe the background to this is the continuously growing global population and the resulting investment in healthcare, which led to a steady expansion of the market size.

Sysmex was able to successfully capture that wave of expansion. In order to capture it, we increased the number of countries and regions where we provide direct sales and service, and expanded our market share in each country. I believe that this enabled us to secure this kind of high growth and high profitability.

Behind that is the fact that Sysmex is a manufacturer that is chosen, a brand that is chosen, and that we provide products that have earned a high level of trust. Furthermore, I believe that the outstanding colleagues at Sysmex who deliver them are what support us. Based on the resources generated through high growth and high profitability, we have been able to invest in new businesses and in DX.

At the same time, I believe that the current situation at Sysmex is that the returns on those investments are lagging behind what we are now expecting.

## Our Strategic Priorities

### Maintaining a strong focus on the diagnostics business

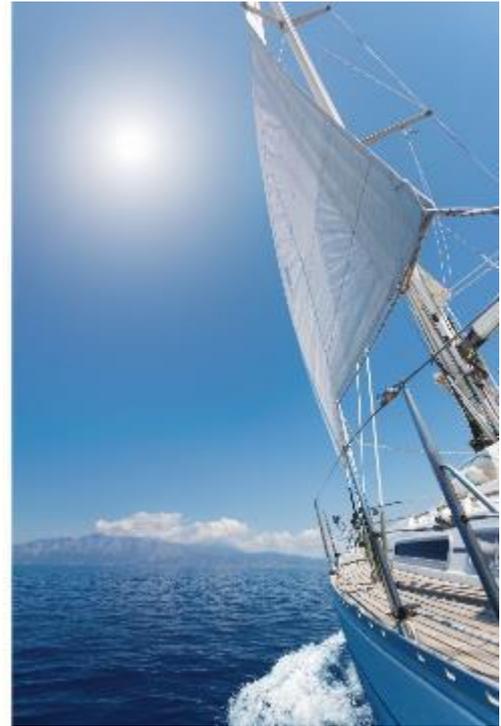
- Launching new products that meet customer expectations
- Create new value through DX

### Building a more cost-competitive and profitable corporate structure

- Improving the profitability of diagnostic reagents
- Improve management efficiency and productivity by utilizing DX
- Conduct a bold review of the business portfolio and R&D themes

### Fulfilling our social responsibilities

- Strengthen a stable supply system that does not stop testing around the world
- Ensure accountability to stakeholders



In light of those circumstances, I have identified three things that I would like to work on in the new mid-term management plan.

The first is that I want us to maintain a strong focus on the diagnostics business. I believe that the number one priority for us as a manufacturer is to provide new products and new offerings that meet customer expectations or exceed customer expectations. In addition, there are many customers around the world who use Sysmex products. I would like us to make the fullest possible use of the customer base and accurate test data generated there to create new value.

The second point is building a more cost-competitive and profitable corporate structure. I would like to improve the profitability of reagents, which are one of our major sources of earnings. We have an integrated value chain, from research and development to customer care. Within this, I believe we can improve the profitability of diagnostic reagents. In short, I believe there are many hints for doing so.

Also, as I mentioned earlier, we have made a considerable investment in DX, and through that, improvements in management efficiency and productivity can be achieved. This is not limited to core systems. Right now, our colleagues are developing software without source code and improving productivity. Including these kinds of initiatives, I would like us to make effective use of DX.

Also, there is pivoting, which my predecessor, Asano, had been pursuing, and I would also like to work on reviewing the businesses and research and development themes here within the this mid-term management plan.

The third and final point is fulfilling our social responsibilities. Recently, there are risks such as geopolitical risk and economic security, and while appropriately managing those risks, we would like to build a system that does not stop testing and that can deliver products stably to customers around the world.

Also, as we are explaining things to our stakeholders in this manner today, we would like to explain the substance of our company sincerely and earnestly.

### Reinforce the strengths and earnings power of the diagnostics business

1. **Successfully execute the global launch of new product lines delivering new customer value**
2. **Accelerate medical DX initiatives that leverage Sysmex's strengths**
3. **Reform our corporate structure to sustain a cost base resilient to global volatility and competition and capable of sustaining stable supply**
4. **Return to a growth trajectory while improving profitability and capital efficiency to enhance corporate value**

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Based on those considerations, these are the aims of the new mid-term management plan.

In fact, the fiscal year ending March 31, 2029, the final year of the next mid-term management plan, will mark the 60th anniversary of Sysmex's founding. We want to become a company worthy of that 60th anniversary, and if I were to put it in one phrase, the aim this time is to reinforce the strengths and earnings power of the diagnostics business.

As measures to achieve this, the following four points are set out. First, new products that deliver new customer value. That is, to launch these globally. Kensuke Iizuka, who will speak after me, will explain the details. As I said earlier, we position this as the number one priority for us as a manufacturer.

Next are Sysmex's strengths. As I mentioned earlier, we have customers around the world, and while making truly effective use of that foundation, we would like to contribute to medical DX here.

The third point, as I mentioned earlier as well, is the global situation, and also the fact that emerging manufacturers are now competing considerably on cost. In response, we also want to strengthen our cost structure and deliver our products stably to customers around the world.

By actually realizing these things, Sysmex will return to a growth trajectory once again. As a result, profitability and capital efficiency will improve, and corporate value will increase. This is the scenario we are envisioning in the next mid-term management plan.

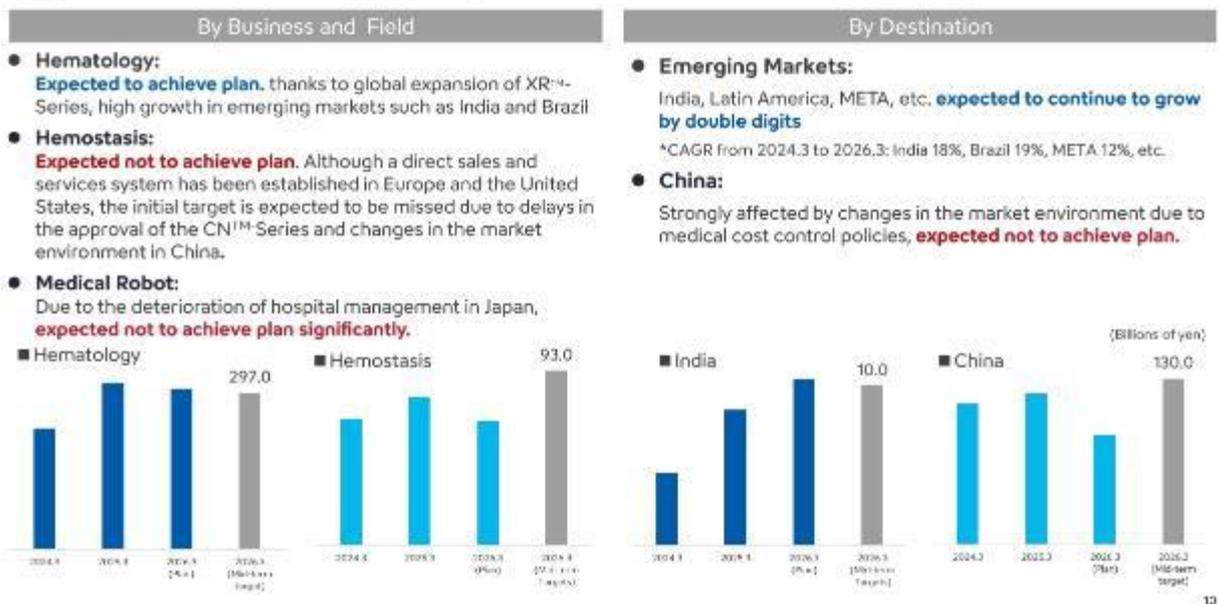
That concludes my explanation. Thank you very much.

**lizuka:** I am lizuka. Now then, I would like to explain the details of the next mid-term management plan.

As many of you may know, under the previous approach, we rolled out the three-year mid-term management plan every two years, but from the current mid-term management plan, we switched to a policy of making the three-year plans successive.

Accordingly, the next mid-term management plan will be a three-year plan starting in the next fiscal year, the fiscal year ending March 31, 2027, and ending in the fiscal year ending March 31, 2029, when, as Matsui mentioned earlier, we will celebrate our 60th anniversary.

### Review of the Previous Mid-Term Management Plan (by Business, Field and Destination)



First of all, I would like to begin by briefly explaining the status of achievement of the current mid-term management plan.

In the hematology field, the new XR-Series have been very well received by customers around the world under the touch-free concept. As a result, performance has exceeded the target figures of the current mid-term management plan.

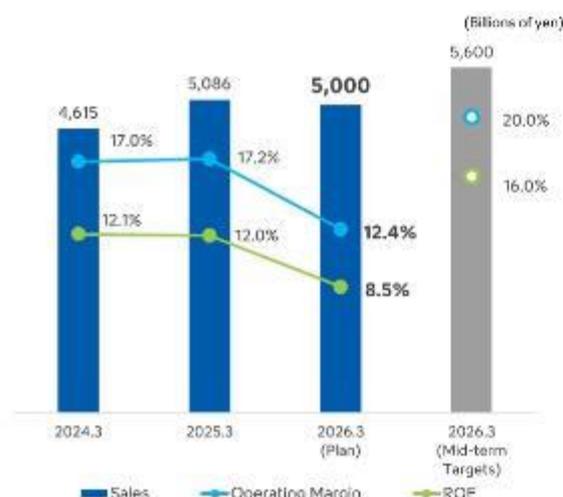
On the other hand, in hemostasis, during the current mid-term management plan period, based on the new contract with Siemens, we have been moving ahead with preparations to promote direct sales support for instruments and reagents, particularly in Europe and the Americas, and we have also completed FDA clearance in the United States in particular, so I believe it can be said that preparations have progressed steadily.

However, with regard to concrete growth in the deployment of hemostasis in Europe and the United States, particularly including the Americas, we believe this can be expected during the next mid-term management plan period after this one.

Then, in terms of regions, particularly emerging countries, growth has been achieved in markets such as India, Brazil, and the Middle East. As shown, these countries have also been progressing in a manner that exceeds the current mid-term management plan targets.

At the same time, however, as we have repeatedly explained, there is China at present. This has, after all, been significantly behind, particularly in the previous fiscal year and this fiscal year, due to the impact of government-led medical cost control policies.

## Review of the Previous Mid-Term Management Plan



### Outlook for Achievement of the Mid-term Management Target

<b>Sales</b>	<b>-10.7%</b>
<b>Operating margin</b>	<b>-7.6pt</b>
<b>ROE</b>	<b>-7.5pt</b>

Expected to miss the target due to a combination of factors

- ✓ China's expansion of healthcare cost control policies
- ✓ Delay in monetization of new business groups
- ✓ Increased internal DX investment and higher SG&A expenses due to inflation, etc.
- ✓ Profit growth below plan and ROE expected to fall short

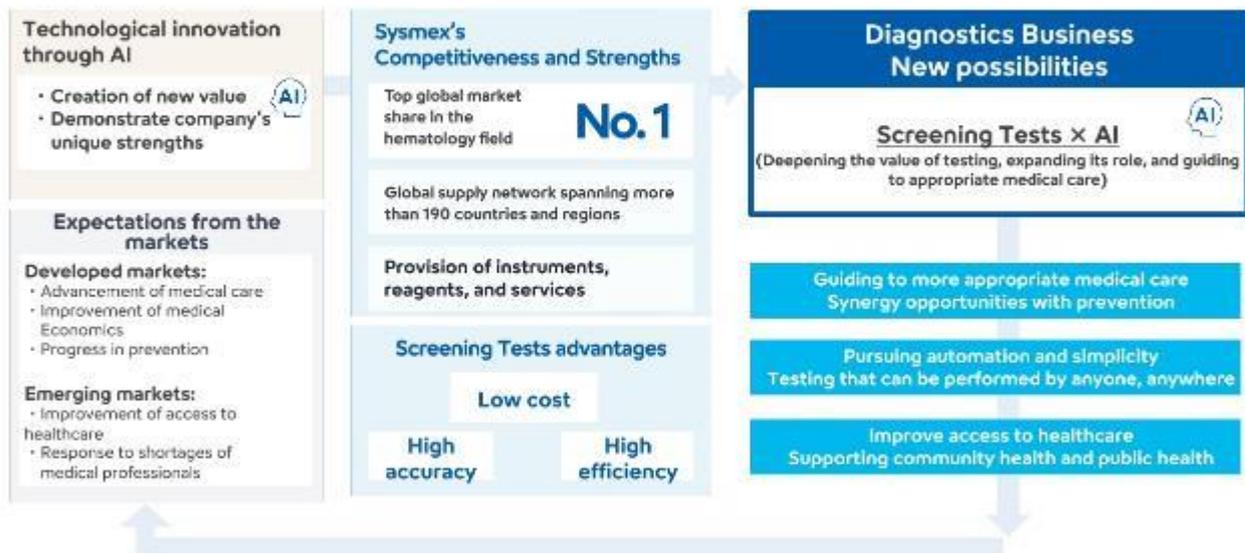
**Even though we have achieved high growth in the field of hematology and emerging countries, there are still issues in both growth potential and profitability, and we expect to miss the target**

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As a result, looking back over the overall figures for the three years, I believe the first year and the second year progressed steadily. However, this fiscal year in particular, that is, the third year, was also affected by the lag in China, and we ended up falling short of the plan. As shown, sales were 10.7% below plan, operating margin was 7.6 points below plan, and the efficiency indicator, ROE, currently stands at 7.5%, resulting in a significant gap versus the plan.

Accordingly, I believe the key point is how we will recover from this situation in the next mid-term management plan.

## Turning Sysmex's strengths into Tangible Growth Opportunities



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From here, I would like to explain the next mid-term management plan.

First, as for the environment, as we have already informed you, in developed countries in particular, against the backdrop of declining birthrates and aging populations, issues such as the advancement of healthcare and improvements in healthcare economics have become apparent as social issues.

On the other hand, in emerging countries, population growth and economic growth are providing support for healthcare infrastructure, and for this reason, healthcare conditions and healthcare needs in these countries remain solid.

At the same time, however, it is not the case that everything is going well, and in these emerging countries, issues such as the decentralization of healthcare, improvement in access to healthcare, and healthcare workers have come to the fore. Although the population is increasing, there is a sense of challenge that these professionals and healthcare workers are in short supply. The same thing is happening in developed countries as well, but how to make up for the shortage of these allied healthcare professionals has emerged as a social issue.

On the other hand, as for Sysmex's strengths, we have customers in more than 190 countries and regions, centered on hematology, and our sales and service network, quality, and brand have been highly evaluated by customers, and we have earned a high market share.

By combining these Sysmex strengths with recent new technologies, including the latest technologies such as AI, I believe that the realization of medical DX unique to Sysmex will be at the center of the next mid-term management plan.



First, regarding strengthening the competitiveness of the diagnostics business, during the next mid-term management plan period, as shown here in the figure, we plan to launch flagship models in each field, including hematology.

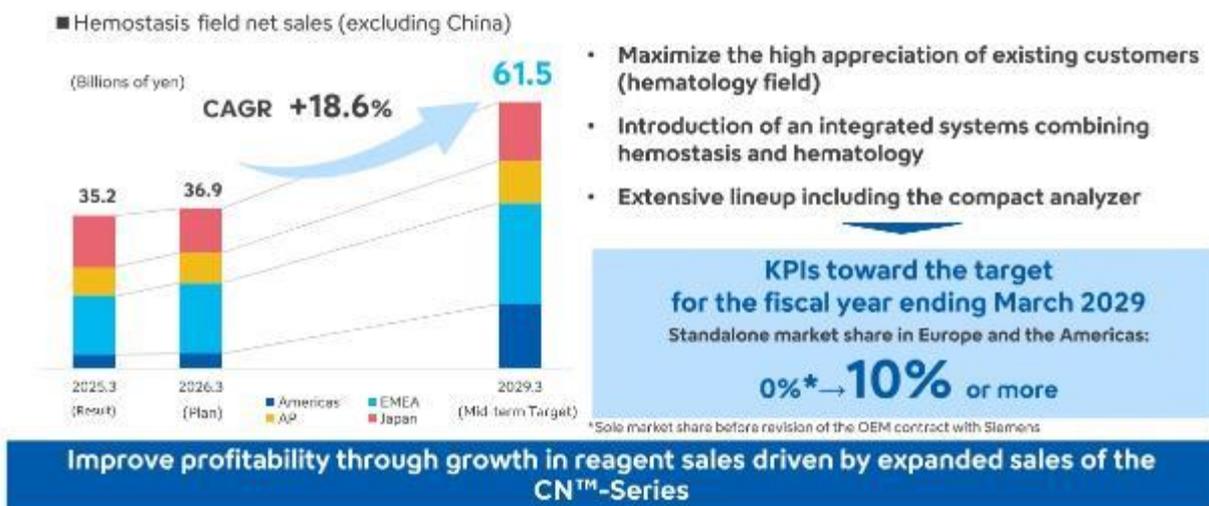
As for these next flagship models equipped with AI, we intend to roll them out not only in the upper-end market, but also in the mid-end and middle to lower-end markets, in a way that provides products suited to the needs of each segment and market.

As for Sysmex AI at the very bottom, I would like that to be discussed in detail later in the R&D meeting.

## 1. Strengthening the Competitiveness of the Diagnostics Business



### ● Accelerate growth in the hemostasis field in Europe and the Americas



Next is the hemostasis field.

As I touched on briefly earlier, during the next mid-term management plan period, we would like to move forward with the deployment of hemostasis, centered on Europe and the Americas. We will promote this with a target of a standalone market share of 10% or more.

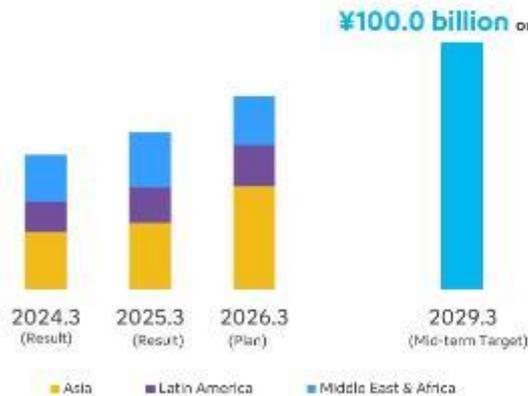
As you know, hemostasis customers and users are the same customers as hematology customers, so in order for customers already using hematology to recognize the value of Sysmex, we intend to actively expand sales in hemostasis as well.

As I mentioned earlier, the preparations required during the current mid-term management plan period are now in place, so from here we will finally begin full-scale sales promotion and roll this out in earnest, and we expect high growth. At first, instruments will take the lead, but as instrument installations progress, reagent sales will naturally expand, so naturally, the expansion of reagent sales will also contribute significantly to improving profitability.

## 1. Strengthening the Competitiveness of the Diagnostics Business



- Achieve double-digit growth in the emerging markets (Asia, Central and South America, the Middle East, Africa, and other regions)



- Introduce strategic products sequentially

- Introduction of our own "tabletop and small models"
- Accelerate reagent sales and improve profitability by utilizing strategic products

- Providing new solutions using medical DX

- Establishment of a public health support model based on a high market share

- Strengthening the direct sales and service system (ongoing)

- Strengthening a stable supply system by utilizing new production facilities (ongoing)

**Capture high-growth markets effectively through strategic products that address customer needs**

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Next are emerging countries.

Here as well, during the current mid-term management plan period, we achieved high growth that cleared the target, and in the next mid-term management plan as well, without stopping this trend and this momentum, we will set a target of JPY100 billion or more in three years.

By introducing strategic products on an ongoing basis, emerging countries do, after all, have issues unique to emerging countries, and these are different from those in developed countries. By rolling out products that meet the needs and requirements of emerging countries, which differ from those of developed countries, we intend to achieve this figure.

Also, we have been implementing this during the current mid-term management plan as well, namely, strengthening the system to support direct sales in these emerging country regions. Here too, while monitoring the situation in each country, we would like to start direct sales as needed and in a timely manner when necessary.

# 1. Strengthening the Competitiveness of the Diagnostics Business (Initiatives in China)



**While revitalizing business activities for future growth, sales for the fiscal year ending March 31, 2029 are expected to be at the same level as the fiscal year ending March 31, 2026**

Next is China.

At present, we are facing headwinds from government-led medical cost control policies, but on the other hand, as announced recently in the five-year plan, which I believe you have seen, China is also placing considerable government emphasis on measures to address the aging population. It has been advocating what is referred to as Healthy China, and we expect that investment to realize this Healthy China will continue to be made under government leadership, so we do not believe that there are only headwinds.

At the same time, however, we expect that to a certain extent, various new systems associated with medical cost control policies, as well as movements such as distributor reorganization in response to those policies, will continue. Therefore, while closely monitoring these developments, we would like to proceed in parallel with preparations so that we can properly ride the next wave of new market growth when it comes.

As in other developed countries, we will strengthen direct sales support. Also, during the current mid-term management plan period, we have basically begun local production in all fields, and while further strengthening that local production, we would like to continue making preparations in parallel. As for sales in China during the next mid-term management plan period, as I will show later, we believe the direction of the market will begin to shift somewhat.

## 2. Advancing Medical DX that leverages the strengths of the diagnostic business



Test Data × AI/Digital = Delivering value unique to Sysmex



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Next is medical DX.

We view the realization of this medical DX as one important theme for us, for Sysmex, during the next mid-term management plan period. Broadly speaking, as shown here, we would like to proceed with three pillars. First, in the center, where it says Operational Excellence, with fully automated laboratories in the future in view, and with that in mind, we would like to advance laboratory safety and reduce manual labor.

As I mentioned at the beginning, this healthcare workforce naturally includes the people working in laboratories as well, and I believe this could become a solution for addressing the shortage of such healthcare professionals.

Next, as for Intelligence Triage shown on the left, this is about enhancing the quality of the results obtained from current screening tests. Hematology testing can at times be simple and low-cost as a screening test. However, on the other hand, because it is only a screening test, there was previously a view that there was a limit to what could be understood, in other words, that the areas that could be understood from screening tests and hematology were reaching their limit, and in that context, there were also movements suggesting that there might be some limit to market growth potential as well.

There were such discussions, but in fact, it is now being found that these screening tests of ours, of course, not limited to hematology alone, may be able to create further clinical value by combining them with new medical DX.

We would very much like to realize this during the next mid-term management plan period and deliver it to all of you. Also, as for the remaining pillar on the right, rather than each individual person's data, this is based on large volumes of data, and particularly as this is becoming a socioeconomic issue in emerging countries, I mean, public health. We believe this may contribute to addressing such issues, and I would like to have this area explained in detail later in the R&D meeting as well.

## 2. Advancing Data Utilization



Internal data × AI/Digital = A High-productivity corporate structure



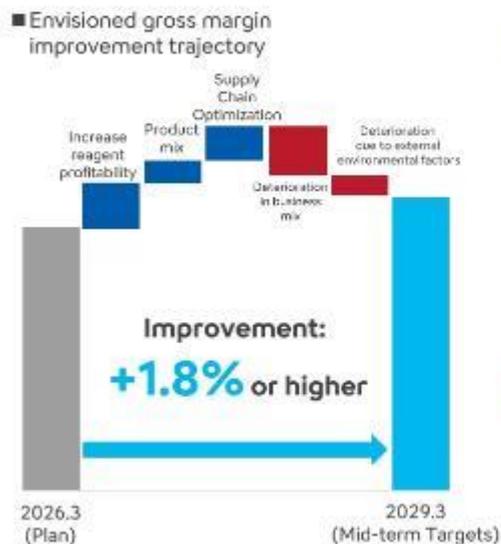
Transform into a corporate structure that continuously improves productivity and efficiency

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Also, we believe that this kind of DX can by no means contribute only to customer-facing solutions, but can of course also make a major contribution to internal processes. As the digitalization investments we have been advancing during the current mid-term management plan period have now been completed, based on globally standardized internal processes and new systems, we would like to further increase process productivity and efficiency.

During the next mid-term management plan period, society will, without question, become one in which people and AI coexist. Our employees' processes will also change into processes in which AI and people work together as a matter of course, so in that sense as well, this can contribute to the appropriate control of labor costs, and as an effect of this, we would like to proceed with a target of JPY10 billion or more over the three years.

### 3. Improving Profitability through Value Chain Transformation



#### Improvement factors

##### ● Increasing reagent profitability

- ✓ Improve productivity through the use of digital information (including production scale optimization)
- ✓ Maintain and increase sales unit prices, promote in-house production of raw materials, etc.

##### ● Improving the product mix

- ✓ Increase the proportion of high-gross-margin products, such as hemostasis reagents.

##### ● Supply chain optimization

- ✓ Optimize global supply chain networks (reducing logistics costs and shortening lead time)

#### Negative factors

##### ● Business field mix

- ✓ Expansion of sales of surgical robot, launch of biochemistry field, etc.

##### ● External environment

- ✓ Decrease in reagents volume and decline in unit price of sales in China, U.S. tariffs, etc.

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In particular, as you know, reagents are a cornerstone of our earnings sources, but in fact, we believe that there is still considerable room to further improve the profitability of reagents. As I mentioned earlier, this is also based on the contribution of the digitalization investments that we have implemented over these three years, and we would like to further improve reagent profitability. Also, as I mentioned earlier in the hemostasis section, we can also expect improved profitability by expanding reagent sales.

Then, with regard to the supply chain, as Matsui also commented earlier, while taking into account various geopolitical risks and economic security issues, we would like to build a globally optimized supply chain network. Through that, we would like to improve the overall gross profit margin.

Of course, as shown in the lower section, there are also negative factors such as the field mix, situation in China, and tariffs in the United States, but while controlling these negative factors so that they can be reduced as much as possible, we would like to increase the positive factors.

## Initiatives Toward New Growth Drivers



### Medical robotics business

- Expand the customer base in the Japanese market
- Enter markets in Europe and parts of Central and South America, in addition to Asia



### Neurology (dementia)

- Early panelization of blood biomarkers
- Accelerate global market entry by leveraging alliances
- Expand the HISCL™-Series globally



### Regenerative and cellular medicine

- Business development across three areas: quality control testing, automation of manufacturing processes, and regenerative medical products
- Accelerate development of themes with strong synergy with the diagnostics business



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Next, businesses other than the core businesses.

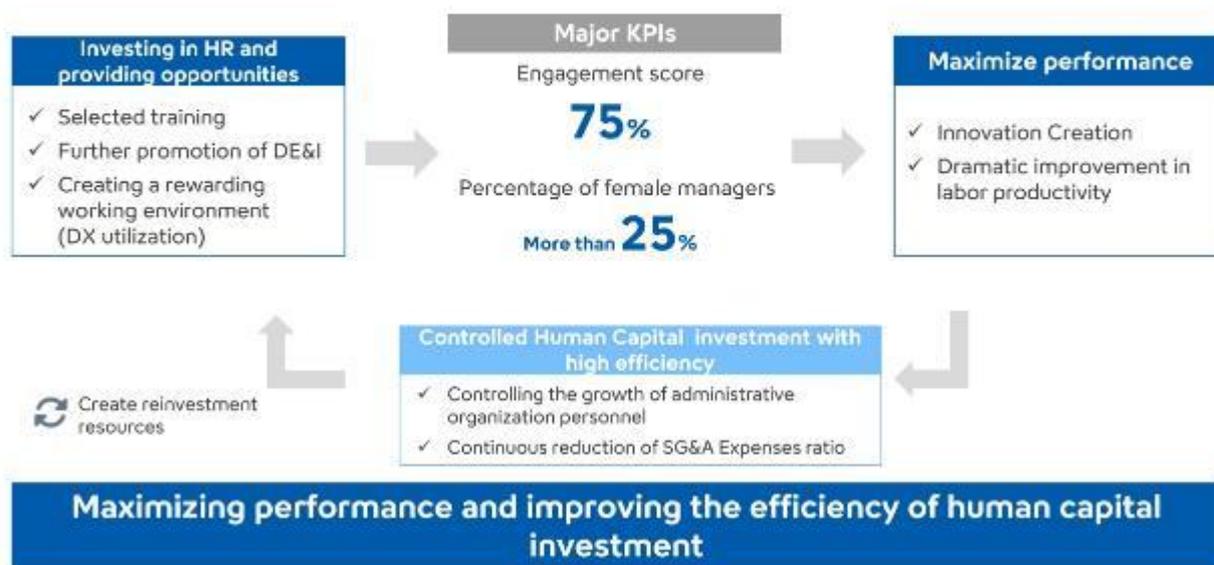
As shown, with regard to medical robotics, Neurology, and regenerative and cellular medicine, we would like to continue to make progress in these areas as well.

With regard to medical robotics businesses, although the result is that we have not achieved the target under the current mid-term management plan, demand at present is very high, and during the next mid-term management plan period, we would like to move forward with global expansion not only in Asia but also in Europe and Central and South America.

However, although demand is very high, these robotic-assisted surgery system are directly tied to life, after all, so as Sysmex's most important issue and theme, more than anything else, quality is our highest priority. Also, customers must be able to use them with confidence. We therefore regard that as the highest priority, and our thinking is that we would like to proceed with deployment steadily, without rushing it, while firmly ensuring these aspects of quality and confidence.

With regard to Neurology and regenerative and cellular medicine, we will explain these in a little more detail later in the R&D meeting.

# Human Capital Strategy



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Human capital strategy.

As I mentioned earlier, the work people do will continue to change more and more from now on. In that context, because we operate our business globally, we want to continue to be a company where people around the world want to work at Sysmex, and where, by working at Sysmex, they can build their dreams or the careers they aspire to. As a result, they can demonstrate their performance, and that in turn contributes to social issues and healthcare issues. That is the kind of company we want to continue to be.

# Financial Targets for the Fiscal Year Ending March 31, 2029

<b>Net sales</b> <b>¥600.0</b> billion or more (CAGR*1 of 6.3%)		<b>Operating profit and operating margin</b> <b>¥100.0</b> billion or more <b>16.7%</b> or more (CAGR*1 of 17.2%) (+4.3pt*2)	
<b>Capital efficiency</b> <b>ROE</b> <b>12.0%</b> or more (+3.5pt*2)	<b>ROIC</b> <b>10.5%</b> or more (+1.5pt*3)	<b>Working capital efficiency</b> <b>Cash conversion cycle (CCC)</b> <b>190</b> days or less (10-day reduction*2)	
<b>Cash generation capability</b> <b>Operating cash flow</b> <b>¥95.0</b> billion or more		<b>Free cash flow</b> <b>¥40.0</b> billion or more	

■ Assumed exchange rates for the period covered by the mid-term management plan  
 1 USD 150.0 yen  
 1 EUR 174.6 yen  
 1 CNY 21.1 yen

\*1: Compound annual growth rate from the plan for the fiscal year ending March 2026 to the fiscal year ending March 2029  
 \*2: Compared with the plans for the fiscal year ending March 2026  
 \*3: Compared with the forecast for the fiscal year ending March 2026

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From here, I would like to explain the specific management numerical targets.

As for net sales, we have set a target of JPY600 billion or more. Also, as shown, we have set targets for operating profit and operating margin of JPY100 billion or more and 16.7% or more, respectively. Then, in terms of capital efficiency, ROE is currently at about 8.5%, below 10%, but we have set a target of 12%, and ROIC is also currently below 10%, but we have set a target of 10.5% or more for that as well.

As for efficiency, various elements are included here, but in particular, we are thinking of improving the inventory turnover period and other areas, and shortening the cash conversion cycle by about 10 days. As for cash, it is as shown.

## Mid-Term Management Plan: Financial Targets



(Billions of yen)

Group Consolidated PL	Fiscal year ending March 31, 2026 (Forecast) * Announced in February	Fiscal year ending March 31, 2029 (Target)	CAGR *
Net sales	500.0	600.0	6.3%
Cost of sales	244.0	282.0	4.9%
SG&A expenses	165.0	182.0	3.3%
R&D expenses	30.0	36.0	6.3%
Operating profit	62.0	100.0	17.2%
Operating margin	12.4%	16.7%	-

\*From the plan for the fiscal year ending March 2026 to the fiscal year ending March 2029

For your reference, we are presenting a comparison between the current forecast for this fiscal year and the goal of this mid-term management plan.

## Mid-Term Management Plan (Sales by Business, Field, and Destination)



### By Business and Field

	Fiscal year ending March 31, 2026 (Plan) * Disclosed in February	Fiscal year ending March 31, 2029 (Target)	CAGR*
Hematology	299.5	334.5	3.8%
FCM	5.0	8.0	17.0%
Urinalysis	46.5	53.0	4.5%
Hemostasis	72.0	93.0	8.9%
Immunochemistry	21.5	25.5	5.9%
Biochemistry	3.0	19.0	85.0%
Life Sciences	24.5	27.5	3.9%
Others	24.5	24.5	-
Diagnostics Business	496.5	585.0	5.6%
Medical Robot Business	3.5	15.0	62.4%
Total	500.0	600.0	6.3%

### Sales by Destination

(Billions of yen)

	Fiscal year ending March 31, 2026 (Plan) * Disclosed in February	Fiscal year ending March 31, 2029 (Target)	CAGR*
Japan	58.0	86.0	14.0%
Americas	139.0	165.5	6.0%
EMEA	161.5	193.0	6.1%
China	86.0	82.5	-1.4%
AP	55.5	73.0	9.6%

\* Compound annual growth rate (CAGR) for the fiscal years ending March 31, 2026 (plan) -2029

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These are the figures by business field and by region.

As for the regional figures, these are shown here in JPY, but in local currencies, we have set targets of USD1 billion for the Americas and EUR1 billion for EMEA.

As for the regional mix, as you know, China accounted for about one-fourth a few years ago, but for the final year of the current mid-term management plan, we have set the target at a level below 15%. I believe the key is how solidly the other regions will grow.

# Materiality



Revised materiality (key issues toward achieving the long-term vision) and reorganized priority themes into six key areas

Priority Themes	Overview
<b>Value Creation for a Healthy Society</b>	Enhancing safety and productivity for healthcare professionals, improving healthcare economics, and improvement in accessibility to healthcare
<b>Creating Innovation</b>	Implementation of innovative technologies and creation and protection of intellectual property
<b>Responsible Provision of Products and Services</b>	Strengthening resilient supply chain, BCP, quality, and compliance
<b>Maximizing Human Capital</b>	Promoting DE&I, talent acquisition and development, and health and productivity management
<b>Environment Consideration</b>	Advancing resource circulation across the product life cycle and reducing GHG emissions and water consumption
<b>Strengthening Governance</b>	Business activities based on legal compliance, respect for human rights, and high ethical standards and cybersecurity measures

Reorganizing related medical related materialities that are directly linked to business and further strengthening linkage with strategy  
Review from the perspective of changes in the external environment, such as the latest technology

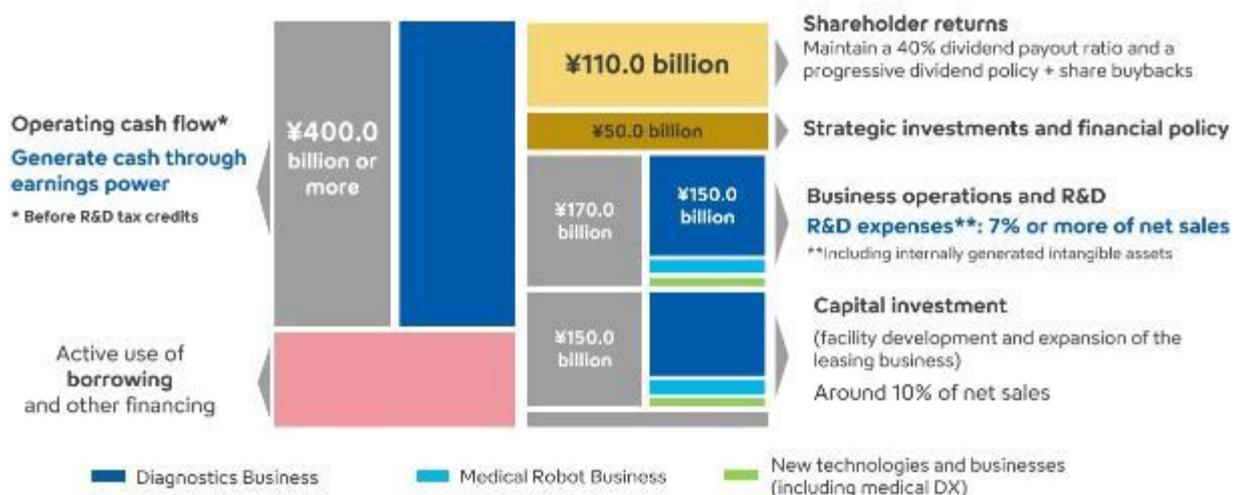
29

Materiality.

As we have been presenting for some time under the concept of double materiality, this time, we have undertaken a new review and have newly set out, in particular, the theme of Creating Innovation as the second item from the top. As I have repeatedly stated, with the implementation of innovative technologies and the creation and protection of intellectual property, creating innovation is naturally indispensable to strengthening diagnostics, including medical DX, so we have included this item.

As for the specific KPIs, we would like to provide separate guidance.

# Capital Allocation (Fiscal Years Ending March 31, 2027–2029)



Prioritize growth investments and allocate generated cash to value creation and shareholder returns

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This is capital allocation. Basically, based on the cash generated by the diagnostics business, while also utilizing debt as necessary, we would like to allocate capital by balancing investments for future growth and shareholder returns.

As Matsui has repeatedly stated, with the strengthening of the diagnostics business, business investments and research and development are shown in dark blue, and we intend to allocate the majority on a priority basis to the diagnostics business. Of course, we will also allocate capital to new areas other than that, but we would like to establish certain limits and control them by setting caps.

We also show capital investment at about JPY150 billion, and at present, we are basically thinking mainly in terms of capital investment that generates cash.

Then, shareholder returns. In the next mid-term management plan as well, we will continue progressive dividends, with a target dividend payout ratio of 40%. Also, with regard to the share buyback that we announced recently, in addition to this share buyback, we would also like to consider and examine share buybacks as needed during the next mid-term management plan period.

Also, if there are opportunities where Sysmex is considered the best owner, we are actively considering M&A as well, and for that reason, we have set aside about JPY50 billion as a strategic investment framework. However, naturally, we do not believe this is an absolute limit, depending on the situation. This is only our current image at this point in time.

## Improving Capital Efficiency and Financial Strategy



As I mentioned briefly earlier, ROE is currently below 10%, but in order to achieve 12% or more, we would first like to realize ROE by improving profitability and profit margin, and also by utilizing capital efficiency and, as necessary, financial leverage.

## Shareholder Returns



### Basic Policy

- Expanding shareholder value through **sustained growth and capital efficiency improvements**
- Continue to invest in growth while **delivering stable returns**
- If opportunities for growth investment are limited, consider further share buyback

#### Dividends

Dividend payout ratio: more than **40%**

Continued progressive dividends

#### Share buybacks

Period: March 2026 ~ September 2026

Total number of shares : up to **30 million**

Aggregate amount : up to **¥30.0 billion**

All re-purchased shares are scheduled to be canceled  
(September 30, 2026)

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Shareholder returns.

This is also as I explained earlier. Basically, we believe that it is important to strike a balance between investment for future business growth and returns to our shareholders, so while monitoring the situation, we would like to implement appropriate measures as necessary. As for the share buyback that we announced recently, it is as shown on the right.

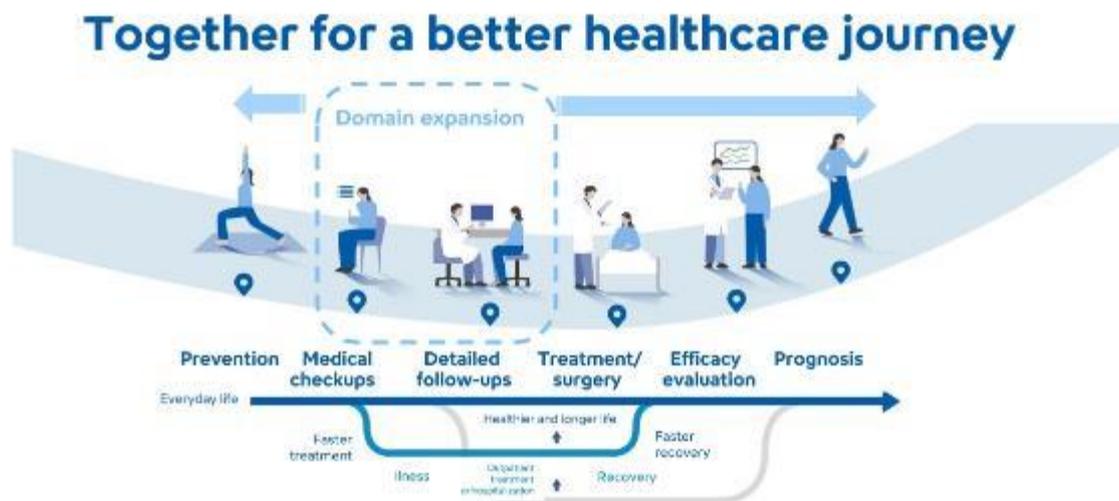
That concludes my explanation.

Thank you very much.

**Yoshida:** Now then, everyone, I am Yoshida of Sysmex, and I would like to begin my remarks at 23rd R&D Meeting.

First, as Matsui and Iizuka explained earlier, from the standpoint of our research and development and technology development as well, we are continuing various initiatives regarding the extent to which we can serve as the engine for achieving the targets of the next mid-term management plan and, beyond that, the targets of the long-term management plan, VA33. I very much hope that you will gain an understanding of those initiatives here.

## Sysmex's Long-Term Vision

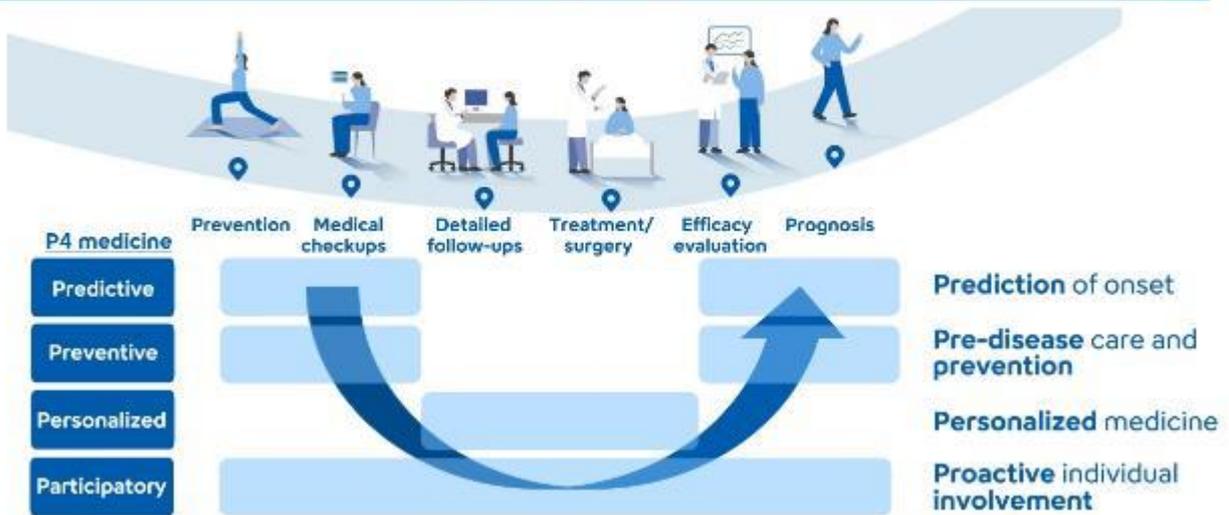


First of all, as you all know, this is part of Sysmex's long-term vision, "Together for a better healthcare journey." As Matsui explained earlier, with regard to the part in this light blue box, domain expansion, one key point, after all, is how strongly we can reinforce diagnostics, which we already have as an existing business, and furthermore, how we can achieve domain expansion by leveraging those strengths.

# Healthcare Journey and P4 Medicine



## Navigating the healthcare journey through the realization of P4 medicine



One key point is how we can expand into what is referred to in society as P4 medicine by leveraging the customer network we have built up to date, our high market share, and our systems and reagents that are fully capable of meeting medical quality requirements.

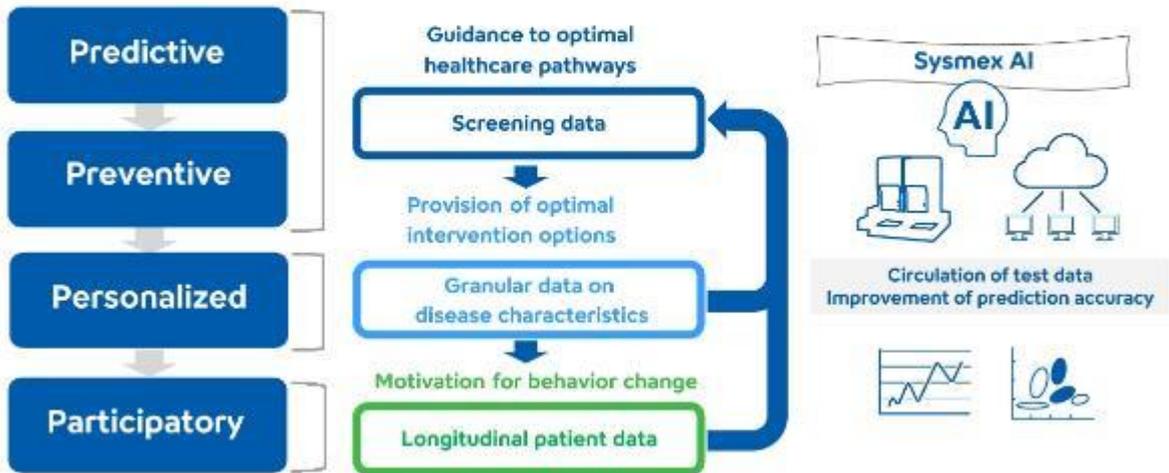
As I explained at the previous R&D Meeting regarding P4 medicine, one key lies in how we can further expand the market, namely, increase the number of people who become customers, through prediction, prevention, personalization, and furthermore participatory involvement by individuals. From here, I would like to explain how we will move forward with the existing diagnostics business that we have been working on to date.

Next slide, please.

## “Data Readiness” for the Realization of P4 Medicine



Utilizing test data to guide patients to optimal healthcare pathways, providing optimal intervention options, and driving motivation



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As for this slide, as the title indicates, one thing we are aiming for is data readiness for the realization of P4 medicine. With regard to this data readiness, one major point is to create, and steadily build up from here, a state in which, starting from the products Sysmex provides, those we have provided up to now, and those we will provide going forward, we can immediately analyze and utilize various kinds of data.

For example, with regard to screening data, there is a wide range of information. Fukuda will later explain the outline of the technology, but not only numerical values such as these, but also analyses obtained from the principles of measurement are showing signs of expanding into the prevention of various diseases, early warning signs, and even treatment.

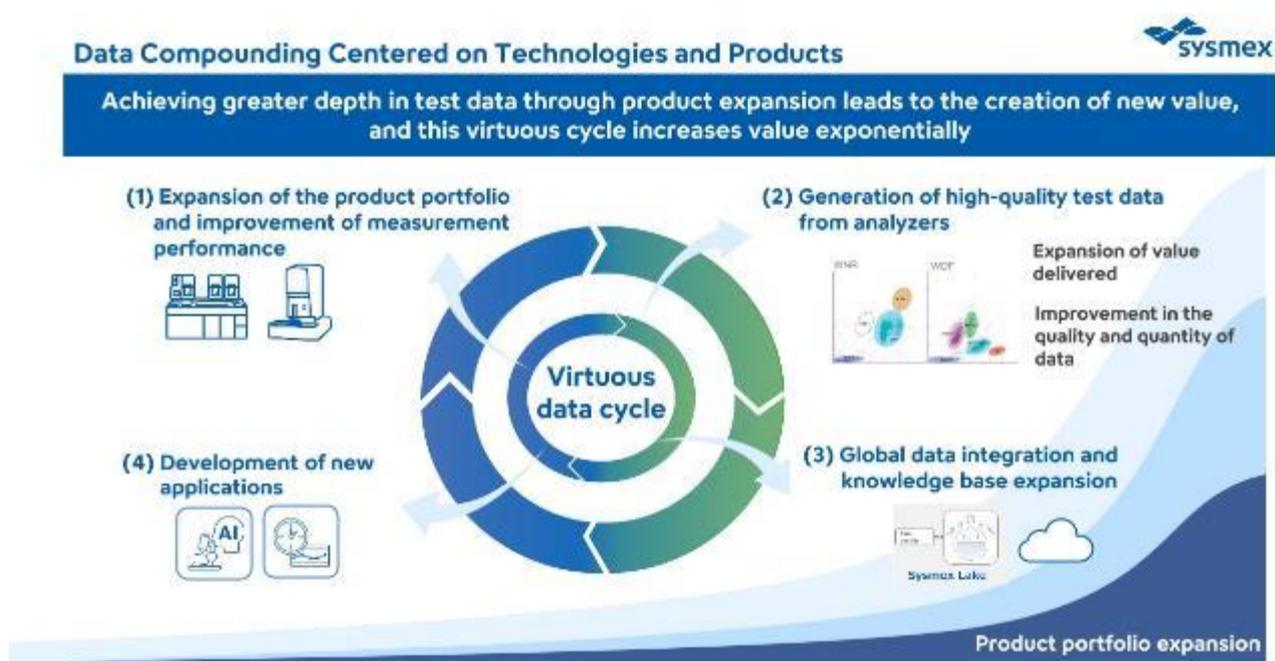
We believe that the quality of such data, the standardized aspects of testing, the potential access to systems deployed globally, and, furthermore, access in the form of metadata to large volumes of data in our daily operations, data that becomes valuable data, will become one major strength for us.



In particular, recently, amyloid accumulation and phosphorylated tau have been taken up as research trends in the market, and how to expand these into routine testing is also one major point. Also, an iPS cell-derived product, the first in Japan, was approved recently. Furthermore, there is also a major government policy in Japan to advance research and development for rare diseases and pharmaceutical research and development.

In light of these developments, when it comes to further enhancing healthcare, I believe the key part is data provided from systems in which medical quality is maintained, and furthermore, the principles and analyses on which that data is produced, namely the significance of biomarkers. I believe the key lies in how we capture these things,, with regard to motivation for behavior change, we have continued to study small immunoassay instruments, and whether such instruments can be used on a routine basis.

Furthermore, together with Nippon Life Insurance, we have been examining how such data can be used. This includes insurance product design, of course, as well as the possibilities in such areas, and we examined these during the current mid-term management plan.



What we are actually thinking is that, with respect to the technologies, products, and medical quality that we have cultivated to date in diagnostics business, we would like to move beyond things that generate earnings power and further compound that data. This concept of compounding indicates that the more data increases, the more the accumulated data generates value in a compounding manner, and we would like to utilize data in that way, and help our customers understand and provide systems that generate data.

As shown in the first point, we will, of course, use AI in expanding the product portfolio and improving measurement performance. From instruments that assure this medical quality, and furthermore from analytical instruments, the question is how we interpret the high-quality data that comes out of them. Naturally, I believe there is a very high possibility that this can also be extended to individual patients.

This is not limited to Japan. It is about how to aggregate, think about, and use the data generated by these instruments globally. We are currently doing this by region in the form of data platforms, and we believe such things can be utilized.

Furthermore, as these data and analyses progress, this will naturally accelerate new development in areas such as systems, applications, and biomarkers.

How to effectively connect the data from each of these individual products, and the data we have received from customers using them, to our business will be a key point in next mid-term management plan as well, and we believe it will be one driving force for achieving VA33.

After my presentation, Fukuda will speak about the new value that can be created precisely because Sysmex products generate medical quality data. Then Iwanaga and Tsujimoto will explain initiatives that could bring about major changes in healthcare and in the healthcare market in the near future.

That concludes my explanation.

Thank you very much.

**Fukuda:** I am Fukuda of the Technology Innovation Division. Now then, I would like to explain the promotion of medical DX through the use of data that Sysmex aims to achieve.

## Creating Value Through Data Utilization



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This slide shows the concept of the value we aim to provide through data utilization. From the beginning, our unique strengths as Sysmex, our core business, are here. We would like to further strengthen the Operational Excellence that we have cultivated here, namely the touch-free concept that we are already advancing, and also work on hospital and laboratory workflow support.

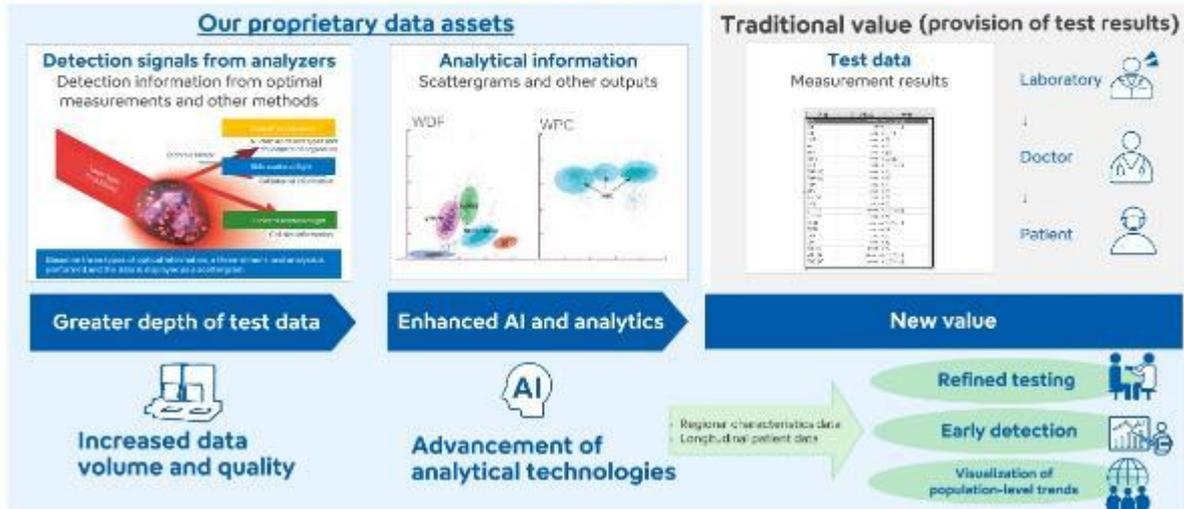
By leveraging the strengths that we have cultivated in our IVD core business, we will refine and enhance the quality of the test data from each analyzer. Using that data, we aim to utilize it in the areas of prevention and early signs to personalization, and further toward the visualization of population trends.

In other words, starting from laboratories and hospitals, and naturally extending to individual healthcare professionals, government, populations, and a broader range of stakeholders, we would like to utilize test data as the source so that we can provide value to many stakeholders.

# Sysmex's Strengths in Medical DX



Expanding the value we deliver by utilizing proprietary data from analyzers, combined with AI and advanced analytics technologies



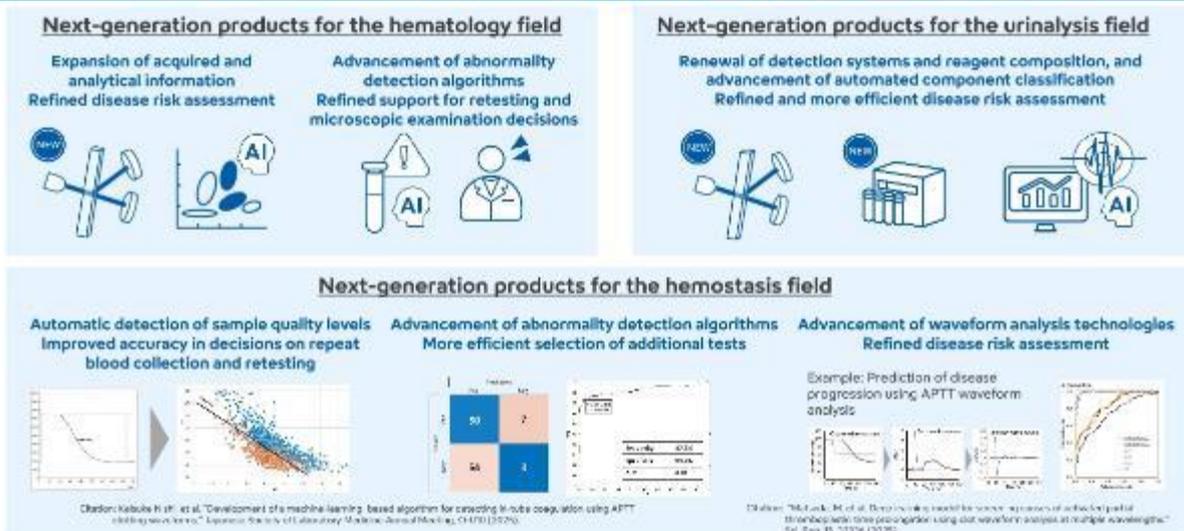
This is an example from hematology field, blood cell count testing, and it is a figure showing where Sysmex's strengths toward medical DX lie. In the figure on the left, there are Sysmex's proprietary data assets. In this figure, in hematology field, cells are detected, a laser is applied, and detection signals are obtained. Through this, the data are developed into analytical information such as scattergrams, and conventionally, delivered to clinical settings in the form of a test data report.

With new platforms and new testing principles, we will further evolve this test data itself. In other words, we will enhance both the quantity and quality of information. Furthermore, by combining this with AI analysis, we are thinking of providing new value in the areas of refined testing, early warning detection, and contribution to populations.

## Refined Testing



Enhancing analyzer-specific data analytics technology through AI integration and utilization  
Leading innovation in testing workflows through testing refinement and efficiency



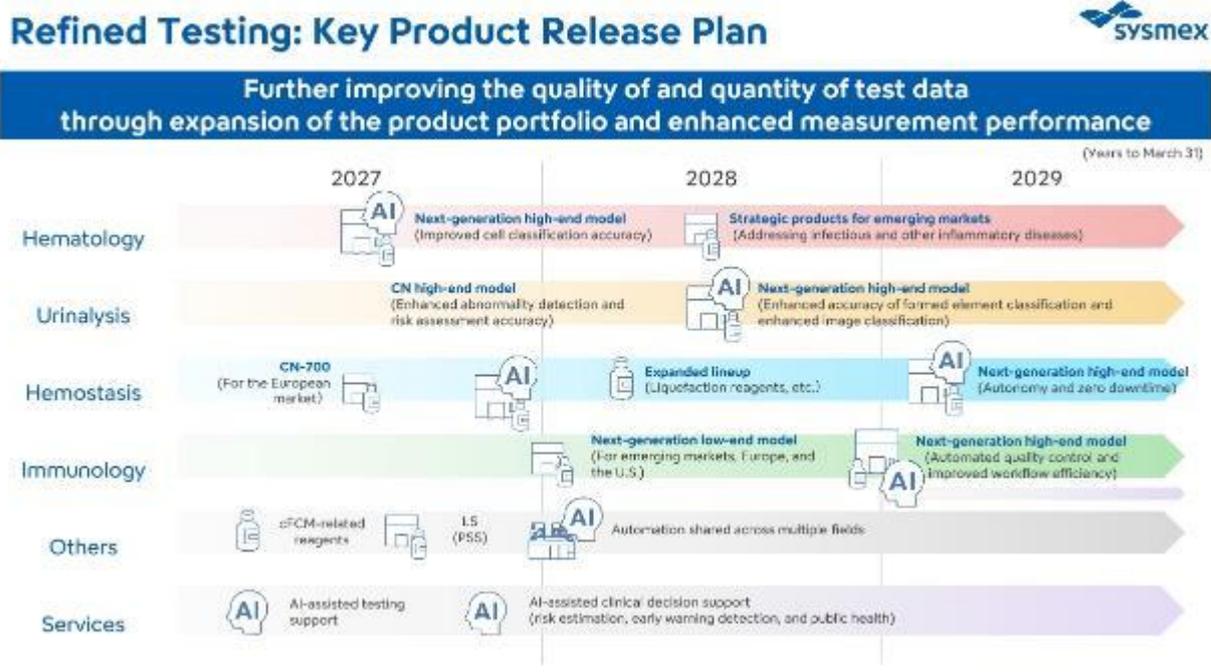
Let me introduce a few examples.

Refining diagnostic testing.

Here, we show the kind of value we aim to provide in Sysmex's core business areas of hematology, urinalysis, and hemostasis testing.

As I mentioned earlier, by deploying new platforms in next-generation instruments in each field and further combining them with AI analysis, we will refine disease risk assessment and evolve algorithms for abnormality determination. In addition, we will further improve the accuracy of cell classification.

The lower section shows an example of hemostasis testing, which we have already presented at academic conferences. By using AI to analyze the detection signal waveforms unique to hemostasis testing, it is becoming possible to deliver new additional value to healthcare professionals and clinical settings, such as the quality of the sample itself used in testing and disease risk assessment.



These are the major products that we plan to release during the period of the next mid-term management plan.

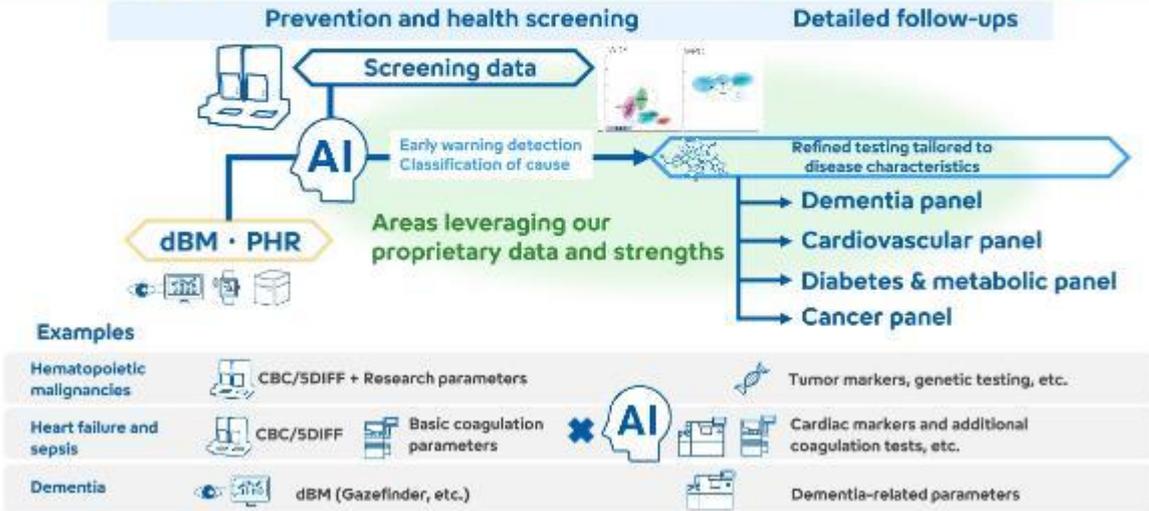
First, we plan to provide the next-generation product in hematology field, as the initial launch, followed by various IVD products equipped with AI. During this period, we intend to firmly introduce to the market and deliver to customer sites what we have developed and promoted to date.

Also, as I will introduce later, as a new AI-centered product, we plan to release an AI solution that will support laboratory and hospital operations.

# Early Warning Detection



Early detection of functional changes using screening data and digital biomarkers  
 Triaging potential causes and seamlessly connecting to detailed follow-ups



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Next, with regard to Early Warning Detection, I would like to explain what we are considering.

This is also a conceptual diagram, but as I mentioned, by refining and enhancing the quality of screening tests, which are a strength of Sysmex's IVD core business, and by combining them with all kinds of medical information and utilizing AI, we aim to connect them seamlessly to disease panels such as dementia and cardiovascular diseases, which are also areas of strength for Sysmex.

For example, in the case of patient samples with hematopoietic malignancies, we are considering detecting warning signs from hematology testing information, as well as from further evolved information, and guiding them to tumor markers and genetic testing.

# Early Detection of Warning Signs for Hematopoietic Malignancies

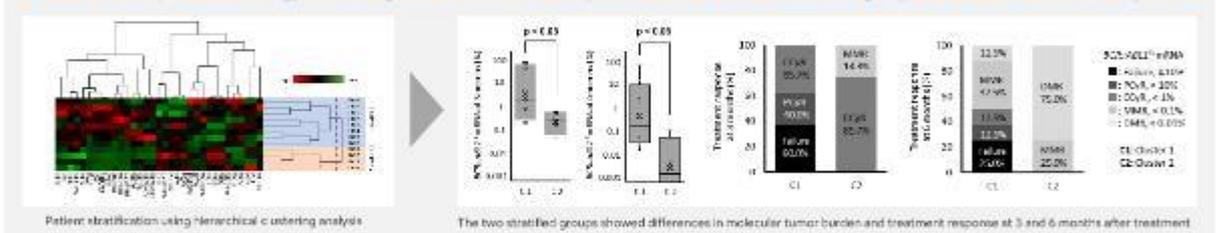


Supporting treatment selection by stratifying patients based on predicted treatment response using hematology data

Example: Chronic Myeloid Leukemia\*

\* Results from joint research with Juntendo University (Source: Suzuki K., et al., medRxiv, Jan 21, 2026)

Multivariate analysis of hematology data at diagnosis demonstrated that patients could be stratified into two groups with different treatment responses



Goal: Supporting treatment selection through prediction of treatment response



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This is an example of that.

Here, while conducting joint research with Juntendo University, by measuring samples and test data from patients with chronic myeloid leukemia and applying multivariate analysis and machine learning to the internal information in this test data, it has become possible to predict treatment response, in other words, to stratify the assessment of treatment effectiveness, and by adding this kind of new information, we would like to deliver appropriate treatment selection tailored to each patient.

## Visualization of Population-Level Trends (Public Health)



Utilizing population-level trend visualization of blood testing data and other applications for public health  
Contributing to healthcare systems and local governance in emerging countries

### Blood test data

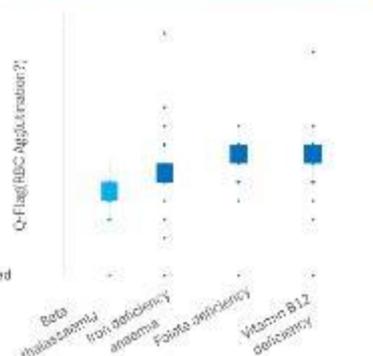
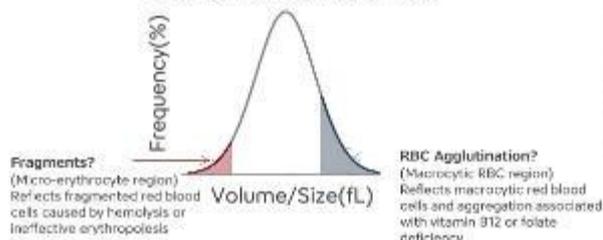


Multiparameter automated hematology analyzer XN-Series

Medical Device Marketing Authorization No.: 28B1KIC014000020

- Examination of differentiation between  $\beta$ -thalassemia and iron deficiency anemia in Pakistan
- Using measurement parameters and research parameters\* from our XN-Series

### Detailed research parameters



Citation/Association: Muhammad Shariq Sheikh, et al. (2025). "Diagnostic Potential of Q-Flag (RBC Agglutination?) and Q-Flag (Fragments?) in Beta Thalassemia: A Comparative Analysis with Nutritional Anemia." 2025 14th International Symposium on Technical Innovations in Laboratory Hematology.

Providing information to estimate disease causes from blood test data and enabling potential visualization of population-level trends

We would also like to contribute to visualizing population trends and to public health.

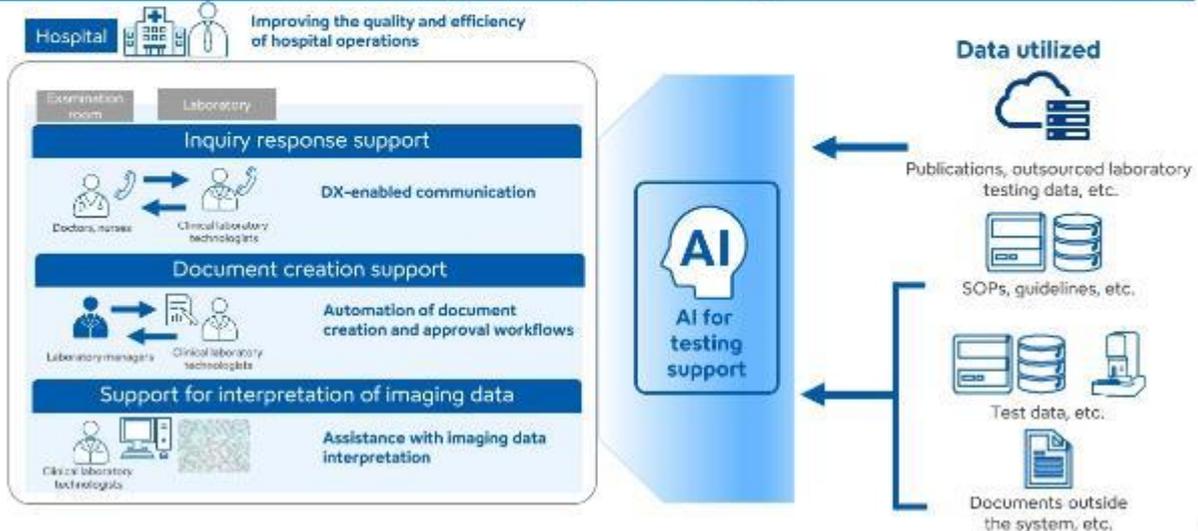
This is a schematic diagram of the results obtained through clinical evaluation and confirmation of clinical performance in Pakistan. Although this is an example from Pakistan, it has become clear that in emerging countries, genetic anemia with a high prevalence,  $\beta$ -thalassemia, and iron deficiency anemia caused by lifestyle-related region diseases can be stratified by analyzing in greater depth the original test signals from conventional research items.

We would also like to introduce such solutions as ones that contribute to public health in emerging country markets.

# Support for Hospital and Laboratory Operations



Reducing the workload of healthcare professionals through data and AI  
Expanding services that address rising medical expenses, healthcare workforce shortages, stricter regulations, workstyle reforms, and other challenges

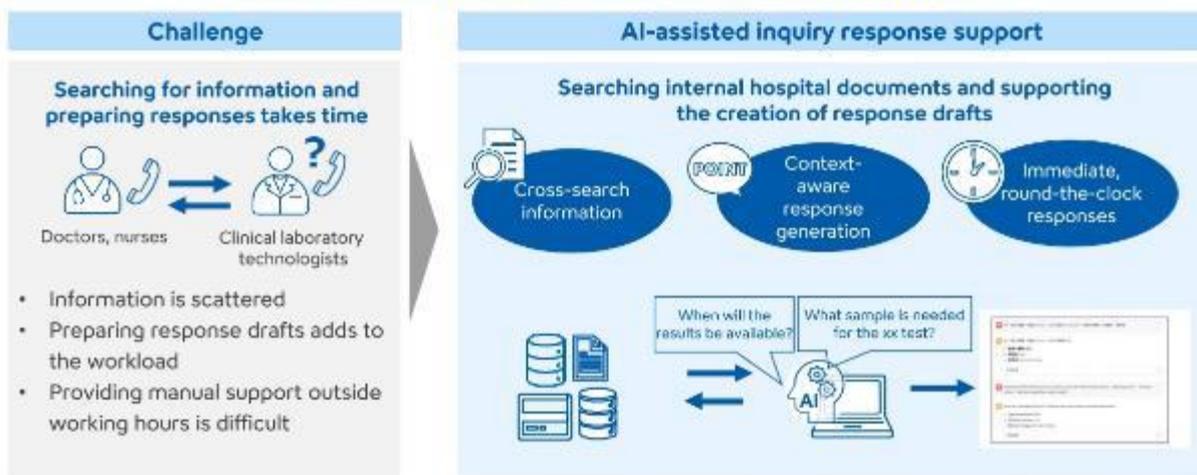


With regard to support for hospital and laboratory operations, as mentioned at the beginning, we understand that in recent years, healthcare settings have been facing various issues, such as rising healthcare costs, shortages of healthcare professionals, tighter regulations, and workstyle reform.

# Inquiry Response Support



Providing immediate answers to doctor inquiries by cross-searching internal hospital documents and test results

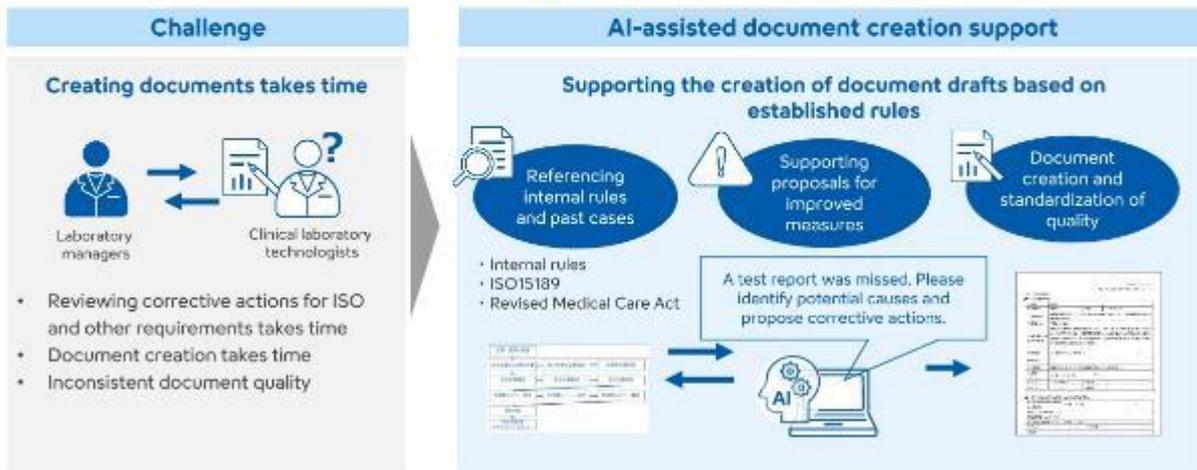


In these areas, by utilizing various kinds of data, here papers, SOPs in laboratories, guidelines, standard documents, and test data, we can use AI to support responses to inquiries, which are cumbersome tasks in laboratories, as well as support document preparation.

## Document Creation Support



### Supporting document creation for ISO and other requirements to reduce the workload of indirect laboratory operations

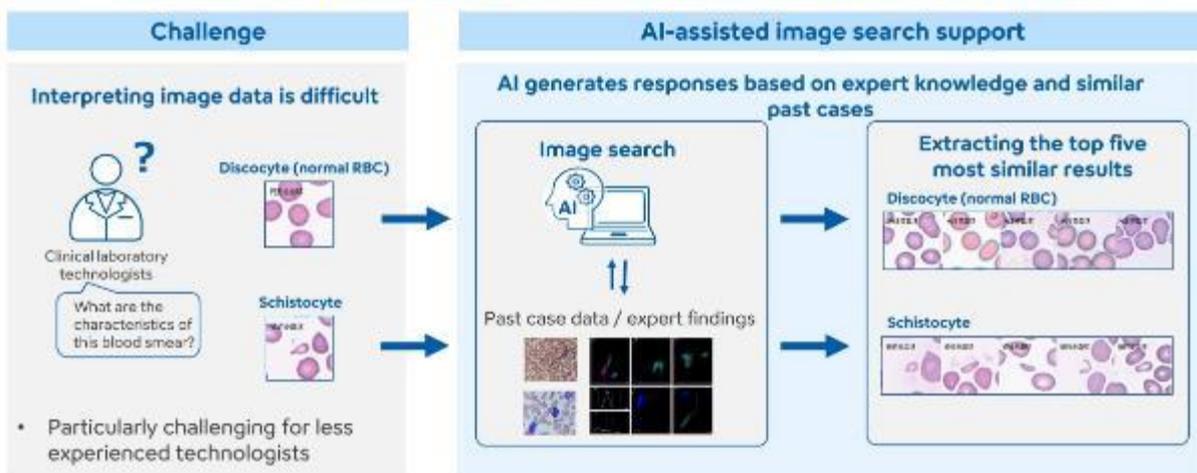


Here as well, we recognize as an issue that a considerable amount of document preparation work is occurring in laboratories and clinical settings, including responses to various matters such as revisions to ISO15189 and the Medical Care Act. We will provide solutions in these areas as well.

## Image Data Interpretation Support



### Supporting searches for past cases and medical literature to promote clinical laboratory technologist education and standardized data interpretation



Furthermore, these are cell images, but with regard to cell images, the scattergrams that we provide, and the interpretation and recognition of such images, their connection with diseases, and the understanding of disease characteristics, there are cases in which interpretation is difficult and challenging even for veteran technologists. In response to this issue, we will also consider new solutions in the form of providing similar images and delivering medical information on their relevance to diseases.

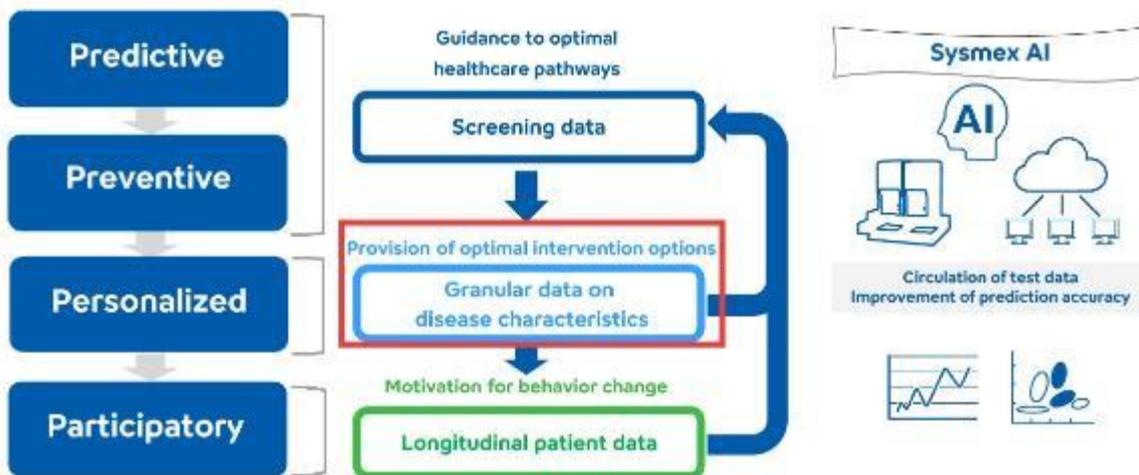
That concludes my presentation.

**Iwanaga:** I am Iwanaga. From my side, with regard to Deepening of Liquid Biopsy Technology, today I would like to give an overview of the theme focused on Toward the staging and stratification of Alzheimer's disease.

## "Data Readiness" for the Realization of P4 Medicine

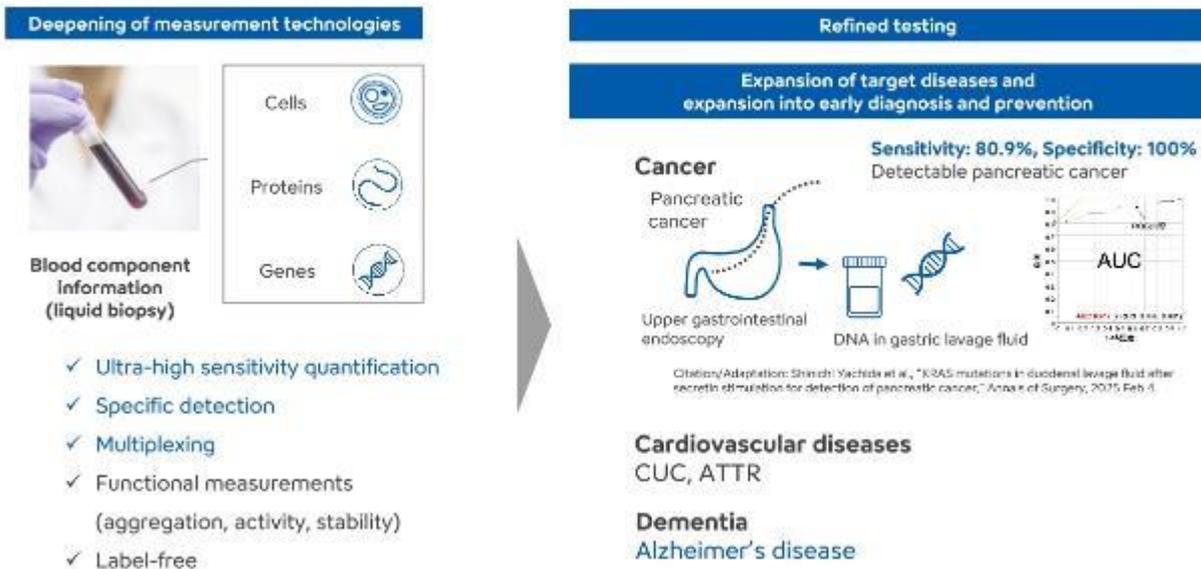


Utilizing test data to guide patients to optimal healthcare pathways, provide optimal intervention options, and drive motivation



This is the material that was explained in Yoshida's presentation. Within this, the part outlined in the red box in the center, Provision of optimal intervention options, is positioned as the acquisition of new technologies for obtaining granular data on patients' disease characteristics.

# Deepening of Sysmex's Liquid Biopsy Technology



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Here, under the heading of the Deepening of Sysmex's Liquid Biopsy Technology, I have provided a brief summary of our initiatives.

At Sysmex, for many years, in the area of liquid biopsy, we have been advancing technologies to better understand patients' conditions by precisely measuring cells, proteins, and genes in blood components.

As written here, we have been studying various technologies such as ultra-high sensitivity quantification, specific detection, multiplexing, functional measurements, and label-free methods, but the key technologies I will explain today are particularly those three points highlighted in color here.

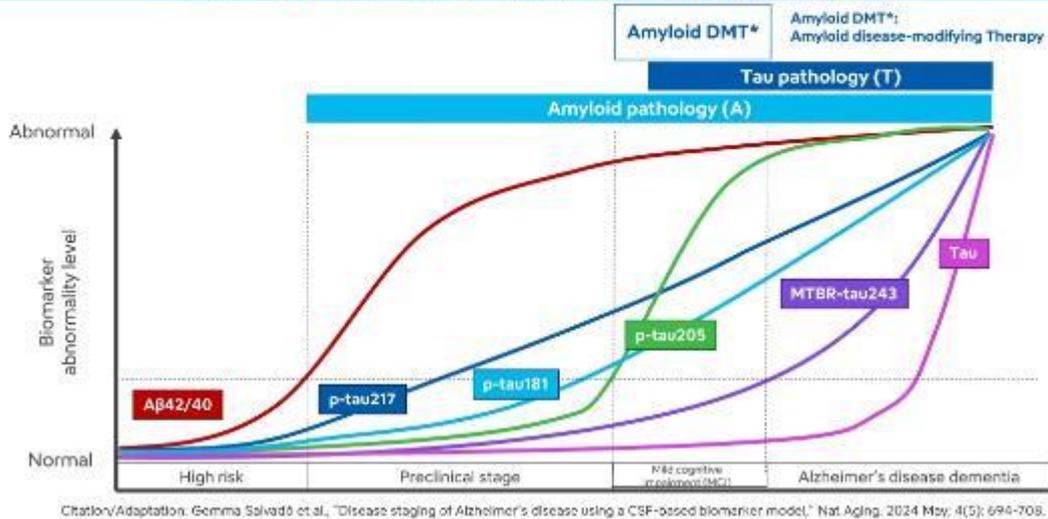
By deploying these liquid biopsy technologies, we have been advancing refined testing, the expansion of target diseases, and the expansion into early diagnosis and prevention. Specifically, in cancer, in testing for pancreatic cancer, by detecting not blood but DNA in gastric lavage fluid using our proprietary artificial diffusion technology, we have acquired a highly accurate pancreatic cancer detection technology with a sensitivity of 80% and a specificity of 100%. At last year's technology briefing, we also introduced a new liquid biopsy in the area of cardiovascular diseases.

In the area of dementia as well, we have been developing blood testing for Alzheimer's disease. Today, I would like to explain this blood test for Alzheimer's disease in detail.

## Blood Biomarkers for Alzheimer's Disease



With the advent of disease-modifying drugs, research and development of biomarkers related to amyloid and tau pathologies is progressing



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This shows the progression of biomarkers in Alzheimer's disease.

In blood testing for Alzheimer's disease, research reports indicate that it is extremely important to examine patients' amyloid status, namely amyloid pathology and tau pathology.

Among these, biomarkers that rise early include Aβ42/40 and phosphorylated tau 217, which I will refer to as p-tau217 from here, while p-tau205 and MTBR-tau243, which reflect tau pathology more strongly, are biomarkers attracting attention in research.

At present, Aβ disease-modifying therapies are being introduced in the market, and treatment is being administered to people with mild cognitive impairment and early-stage Alzheimer's disease. Along with the progress of these therapies, research and development of these biomarkers are also advancing.

## Development Status of Therapeutic Drugs and Blood-Based Diagnosis

Following the rollout of therapeutic drugs around the world, approval of blood-based diagnosis is also progressing.

				
Therapeutic drugs	Leqembi Kisunla	Approved (30 countries)	Approved	Approved
	A $\beta$ 42/40 (Sysmex)	IVDD declared	Application in preparation (Launched in Hong Kong and Macau)	Approved
	p-tau217/A $\beta$ 42 (Sysmex)	Application in preparation		
IVD reagent	p-tau217/A $\beta$ 42 (Fujirebio)	RUO	Pharmaceutical approval (December 2025)	Approved (May 2025)
	p-tau181 (Roche)	IVDR		Approved
	A $\beta$ 42/40, p-tau217 (C2N Diagnostics)	IVD (UK)		
	ApoE Gene (Sysmex)	Application in preparation		Approved (June 2025)

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This is a summary of the development status of therapeutics and diagnostics.

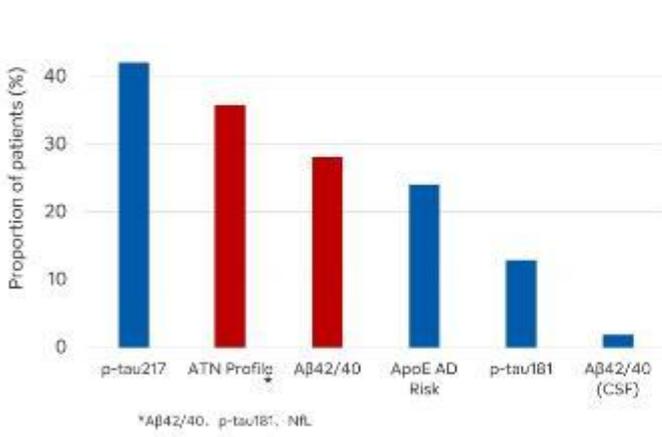
As for therapeutics, treatments such as Leqembi and Kisunla have been approved in countries around the world, and treatment is now in a ready state.

In contrast, with regard to blood-based diagnostics, deployment has not yet progressed around the world, and our A $\beta$ 42/40, Fujirebio's p-tau217, and Roche's p-tau181 have begun to obtain regulatory approvals in regions around the world.

At Sysmex, we are deploying A $\beta$ 42/40 in Europe, Japan, and the United States, and more recently, we are also advancing reagent development for p-tau217.

Also, in the area of the ApoE gene shown at the very bottom, in the area of new technologies and genetic testing for diagnosing adverse effects of Alzheimer's disease, we have obtained approval in Japan this fiscal year. We are now preparing to expand this to Europe as well.

**Not only p-tau217 but also Aβ42/40 reagents are used in combination.**



Research framework proposed by the National Institute on Aging and the Alzheimer's Association (ATN profile)

		Stages of dementia (cognitive impairment)					
		A	T	N	Normal	Mild cognitive impairment (MCI)	Dementia
Biomarker profile	-	-	-	-	Normal		Non-AD
	+	-	-	-			AD-like dementia
	+	-	+	-			AD and Non-AD
	+	+	-	-	Preclinical AD	Prodromal AD	
	-	+	+	-			
	-	+	-	+			

Citation/Adaptation: Real-world patterns of Alzheimer's disease biomarker testing: Insights from a large-scale clinical dataset  
 Citation/Adaptation: Clifford R. Jack, Jr, et al, *A/T/N: An unbiased description classification scheme for Alzheimer disease biomarkers*, Neurology® 2016;87:539-547

With regard to the status of utilization of these blood biomarkers, for your reference, I would like to explain the situation as reported by US commercial laboratories.

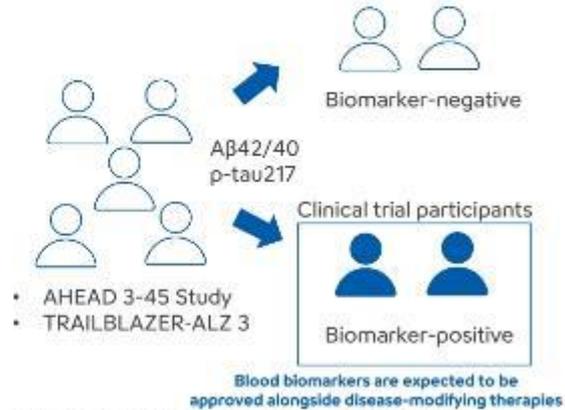
Here, p-tau217 appears to be the most widely used biomarker, but in addition to that, reagents that measure the Aβ42/40 ratio are also used in combination. In the ATN Profile shown by the red bar graph, it has been reported that biomarkers are being utilized in ways that measure multiple biomarkers for classification involving amyloid, tau, and neurodegeneration.

**Early application of amyloid disease-modifying therapies and progress in research and development of tau disease-modifying therapies. Blood biomarkers are used for clinical trial enrollment**

■ Trends in disease-modifying therapies

- **Verification of earlier application of Aβ-targeting disease-modifying therapies**  
Lecanemab, etc.
- **Development of tau-targeting disease-modifying therapies**  
Etilanetug,  
BIB080,  
JNJ-63733657, etc.

■ Utilization of blood biomarkers in clinical trials



Citation/Adaptation: Viswanath Devarajayan et al. Plasma p-tau217 predicts cognitive impairment and amyloid-beta levels in preclinical and early Alzheimer's disease. *Alzheimer's & Dementia* 2024; 20(5):1617-1628  
 Citation/Adaptation: Cook-Berlin Moore-Henry et al. Risk of cognitive decline in plasma biomarker-eligible for a preclinical Alzheimer's disease trial. *Alzheimer's Dementia* 2024; 20(5):1627-1630  
 Citation/Adaptation: Roy Yee et al. Lecanemab in preclinical Alzheimer's disease: Screening and baseline data from TRAILBLAZER-ALZ 3. *Alzheimer's Dementia* 2025; 21(1):106-112

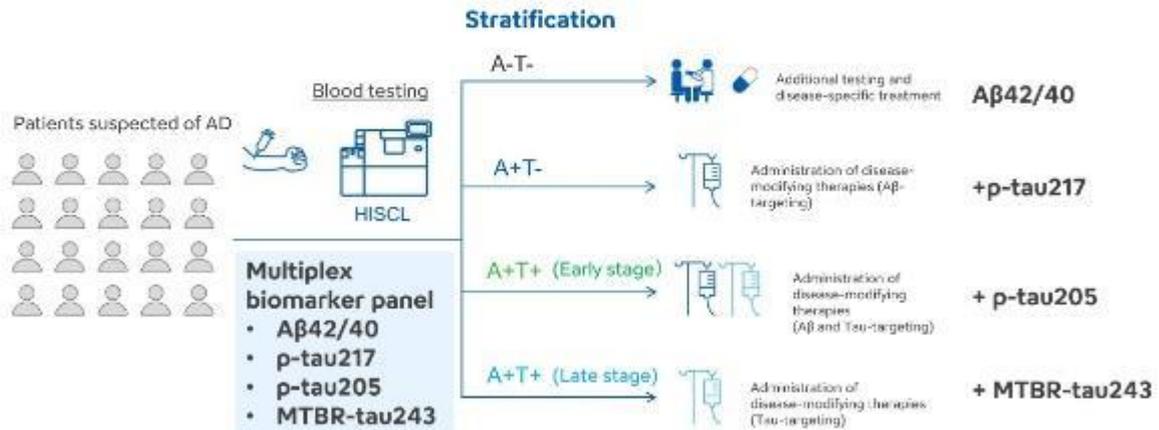
Along with the progress of these therapeutics, development in the area of diagnostics is also advancing, and there are broadly two directions in the research and development of disease-modifying therapies. One is the expansion to earlier stages of the amyloid disease-modifying therapies that have obtained approval to date, and lecanemab and others have now begun such studies.

The other is that research and development and clinical trials of tau disease-modifying therapies related to tau pathology are progressing.

Against these two trends, we at Sysmex are also advancing research and development so that we can acquire diagnostics in parallel.

Also, in these newly advancing findings, new study approaches are emerging in which blood biomarkers are used for patient stratification and treatment candidates are selected. We believe that this trend may also lead to a situation in which diagnostics are approved at the same time as drugs are approved.

## ATN profile enables selection of appropriate tests and treatments

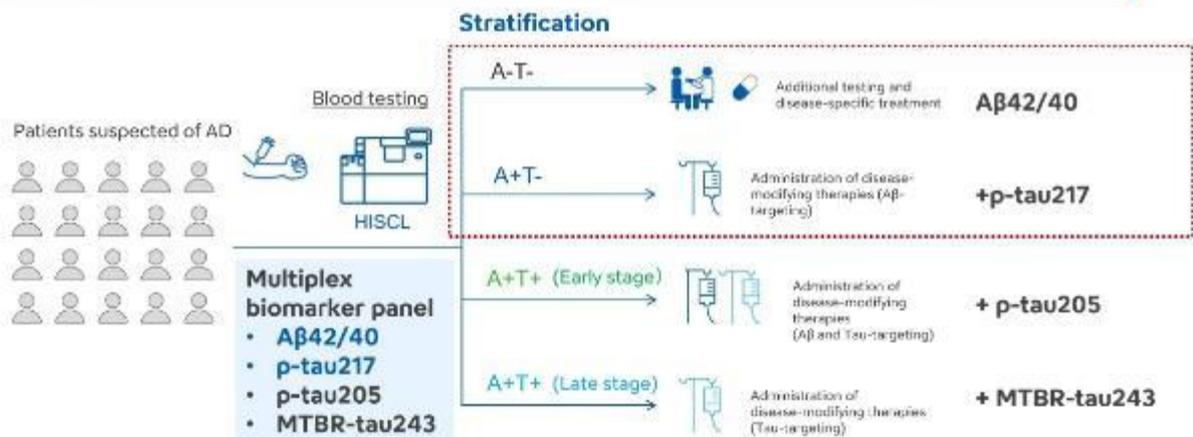


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Against this backdrop, at Sysmex, toward the staging and stratification of Alzheimer's disease, we are preparing a biomarker panel using HISCL that measures multiple biomarkers, as shown here. By using these biomarkers, we would like to correctly classify A, T, and N and realize the appropriate stratification of treatment candidates.

At the earliest stage, this would be carried out using Aβ42/40. For the subsequent amyloid deposition stage, phosphorylated tau-217 would be used. For the tau pathology stage after that, we are advancing research and development on the premise that p-tau205 and MTBR-tau243 may be used.

## ATN profile enables selection of appropriate tests and treatments



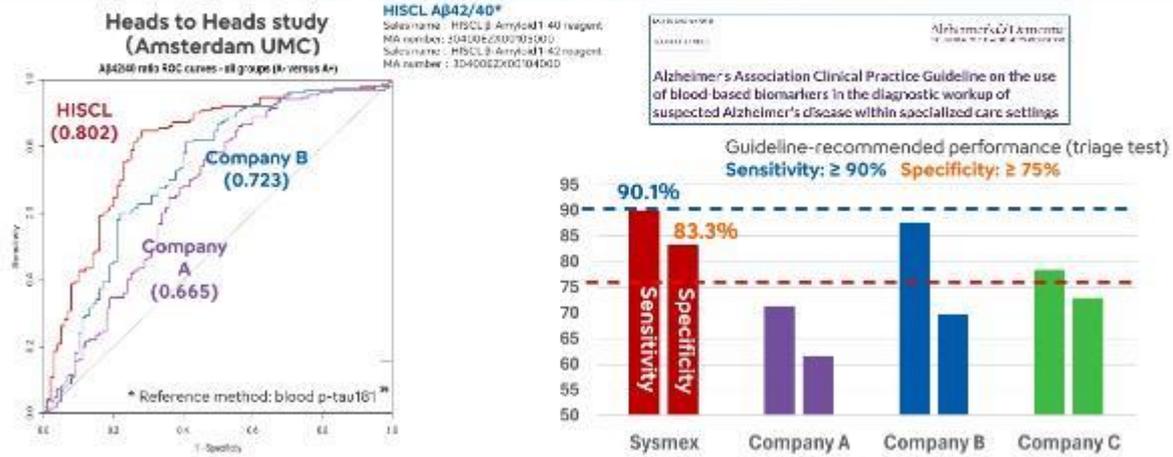
36

Now then, first, I will explain the current status of blood biomarkers that reflect amyloid pathology.

## Amyloid Pathology-Based Stratification Using HISCL™ Aβ42/40\*



In comparative studies with other companies, our system demonstrated performance superior to that of competing products; for Aβ42/40, our system is the only one that meets the guideline-recommended performance criteria



Citation/Adaptation: Inge, V., et al. "High diagnostic performance of the random-access HISCL 5000 pTau217, Aβ42 and Aβ40 plasma assays for detecting amyloid pathology across the Alzheimer's disease clinical continuum." CTAD (2025).  
Citation/Adaptation: Swadlow palmyer et al. "Alzheimer's Association Clinical Practice Guideline on the use of blood-based biomarkers in the diagnostic workup of suspected Alzheimer's disease within specialized care settings." Alzheimer's Demerit, 21(7), e70583 (2025).

What is shown here on the left is the result of comparing the performance of our HISCL Aβ42/40 with the performance of Aβ42/40 offered by various companies. These are the results of research conducted at Amsterdam UMC, and as you can see, it has been confirmed that HISCL shows the best figures and the best performance, as indicated by the solid red line.

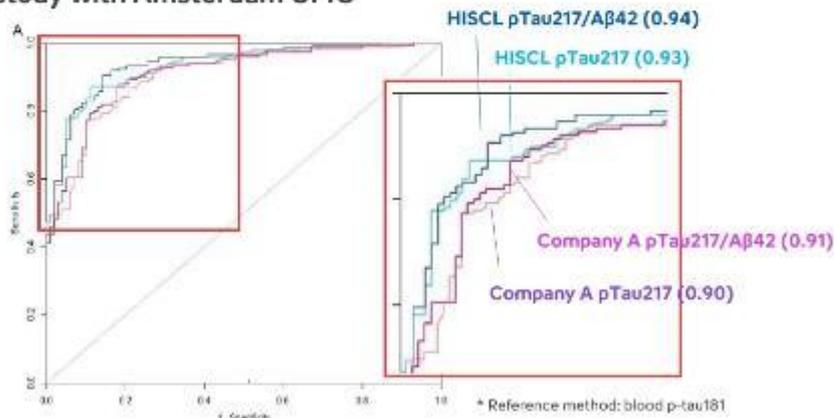
Also, with HISCL, when using the guideline-recommended performance and triage test recommended in the guidelines last year, a sensitivity of 90% or higher and a specificity of 75% are shown. The fact that our product alone is the Aβ42/40 reagent that delivers that performance is what has been confirmed.

## Amyloid Pathology-Based Stratification Using HISCL p-tau217



For both p-tau217/Aβ42 and p-tau217, our system demonstrated superior performance over competing products

### Joint study with Amsterdam UMC



Citation/Adaptation: Inge, V., et al. "High diagnostic performance of the random-access HISCL 5000 pTau217, Aβ42 and Aβ40 plasma assays for detecting amyloid pathology across the Alzheimer's disease clinical continuum." CTAD (2025).

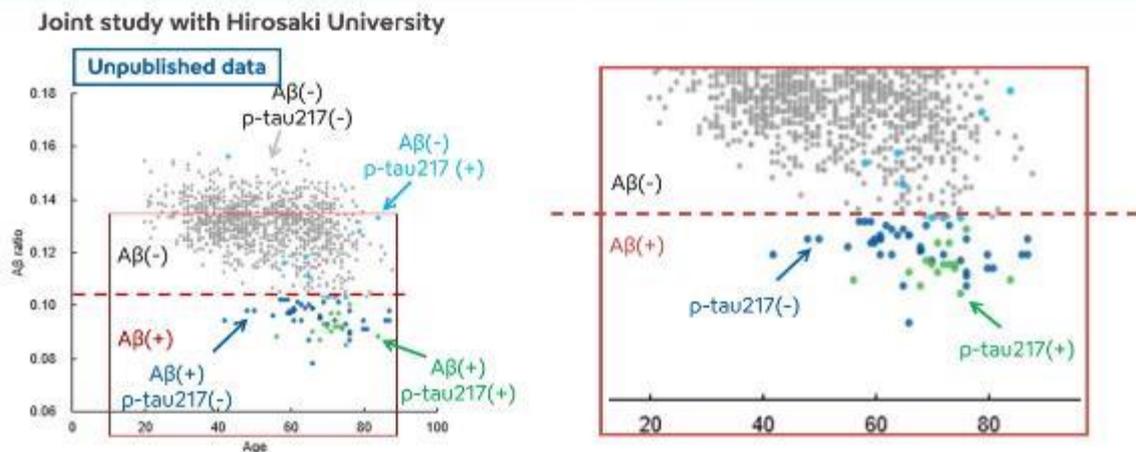
Also, with regard to HISCL p-tau217, which we are newly advancing in development, performance verification has also been carried out by Amsterdam UMC.

But if you look at the enlarged figure on the right, it has been confirmed that HISCL p-tau217/A $\beta$ 42 shows the best performance, followed by p-tau217, and that it demonstrates superior performance compared with other companies' products.

## Early Detection of Amyloid Pathology in a Healthy Cohort



p-tau217-negative cases were observed among blood A $\beta$ -positive individuals; these findings suggest that p-tau217 becomes positive following A $\beta$  positivity



This work was supported by the Japan Science and Technology Agency (JST), Grant Number JPMJCE1302, JPMJCA2201, and JPMJPF-2210

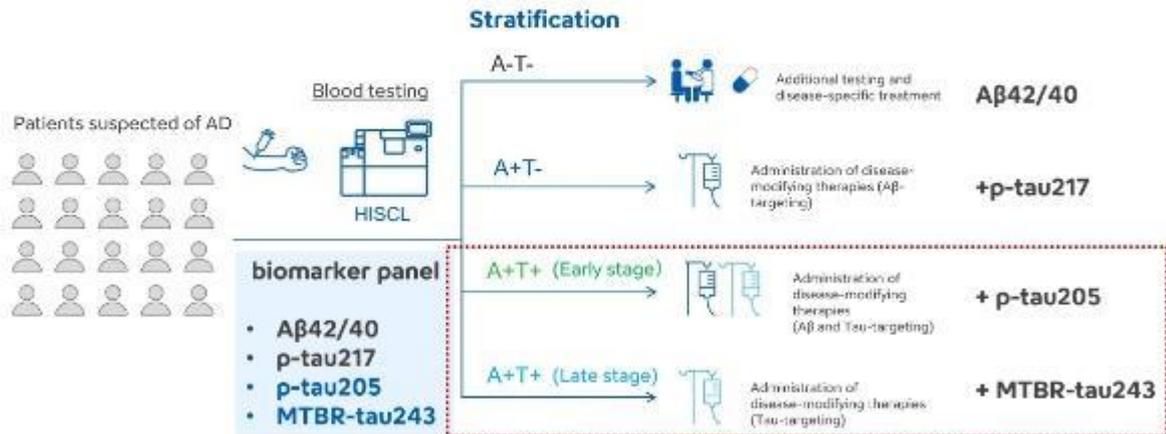
39

Also, as I explained briefly earlier, we have shown that amyloid beta is an early biomarker in Alzheimer's disease. We are also advancing research and development in this area, and in joint research with Hirosaki University, we are studying the amyloid status of a healthy cohort.

Here, the vertical axis shows the A $\beta$ 42/40 ratio value, and the horizontal axis shows the age of the subjects. The area below the red dashed line represents those who are A $\beta$  positive, and among those individuals, the blue circles indicate subjects who are p-tau217 negative, while the yellow-green side indicates those who are p-tau217 positive. As you can see, in the younger age group, p-tau217 is negative, while as age increases, p-tau217 becomes positive.

This is in line with what other researchers have also reported, namely that p-tau217 becomes positive following A $\beta$  positivity, and we are obtaining results that suggest that A $\beta$  may be the biomarker that rises earlier, as we have been considering.

## ATN profile enables selection of appropriate tests and treatments



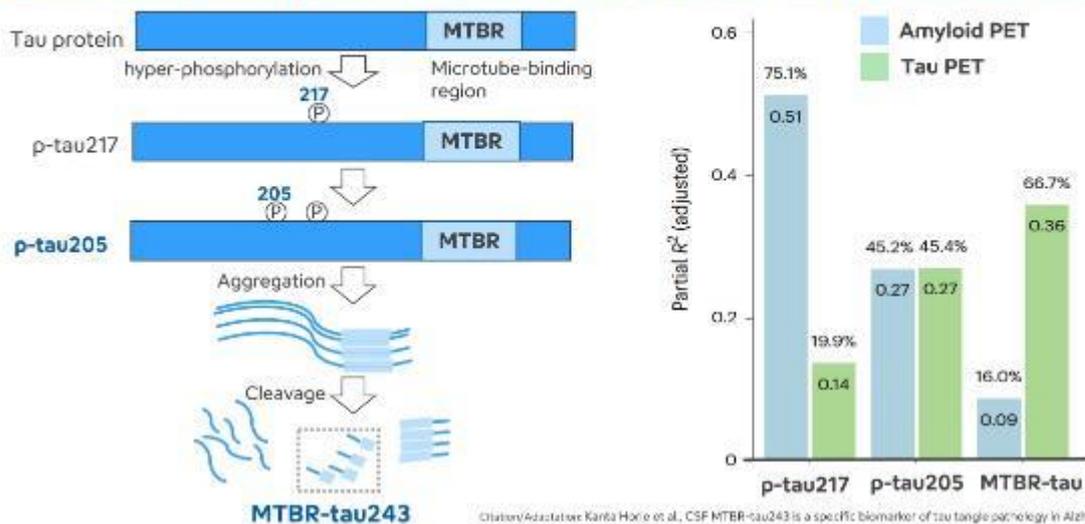
40

Against this backdrop, for testing amyloid pathology, we believe it may be effective to combine Aβ42 and 40 and p-tau217 appropriately so that testing can be advanced properly from the early stage to the late stage.

From the next slide, I will explain research on biomarkers that reflect tau pathology.

## p-tau205 and MTBR-tau243

### MTBR-Tau243 are generated by cleavage of tau proteins Association with tau pathology increases in the order of p-tau217, p-tau205, and MTBR-tau



Chitambar/Adaptation: Karita Horie et al., CSF MTBR-tau243 is a specific biomarker of tau tangle pathology in Alzheimer's disease. Nature Medicine 29, 1954-1963 (2023)

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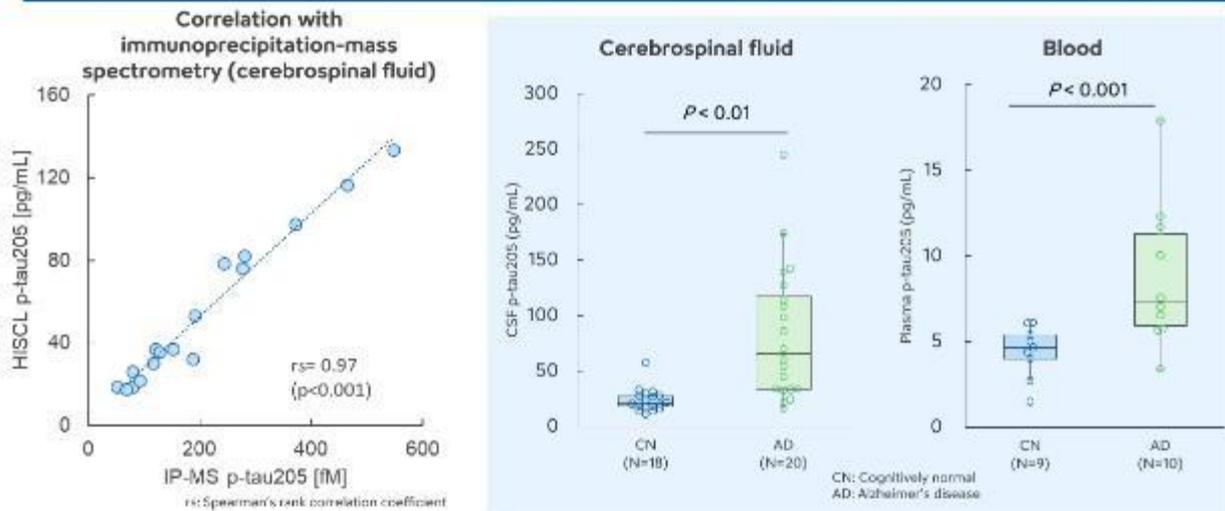
These are the markers p-tau205 and MTBR-tau243, and both are biomarkers derived from tau protein. p-tau205 is generated when tau protein undergoes hyperphosphorylation. A very closely related molecular species is p-tau217, which is a marker in which the phosphorylation site differs slightly. In contrast, MTBR-tau243 is produced when tau protein aggregates, and part of it is cleaved off.

The figure on the right shows how these molecular species differ. Research reports have shown that their reactivity to amyloid PET and tau PET differs, respectively, and we believe that by measuring multiple markers of this kind, it may become possible to determine amyloid status and tau status more accurately.

## Development of the HISCL p-tau205 Reagent



Development of the testing reagent capable of detecting p-tau205 in cerebrospinal fluid and blood



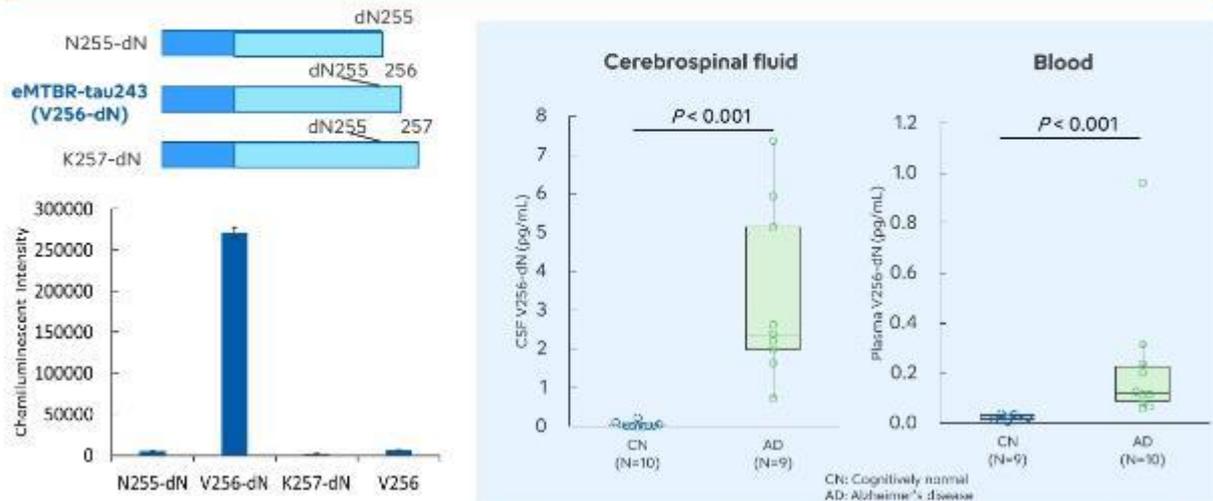
Citation/Adaptation: Ishii, K., et al., "Development of a highly specific p-tau205 assay using a fully automated immunoassay system." ADPD 2025.  
Citation/Adaptation: Murakami, S., et al., "Development of Plasma p-tau205 Assay Using a Fully Automated Immunoassay System." The 44th Annual Meeting of Japan Society for Dementia Research, 2025.

Using HISCL, we are advancing the development of a reagent for measuring p-tau205. Using the same strategy as for developing the amyloid beta reagent, namely first selecting combinations of antibodies that correlate very well with mass spectrometry, we have likewise obtained results showing a very strong correlation for this p-tau205-measuring reagent as well, and, as shown on the right, we are in a situation where we have successfully developed a reagent that can clearly distinguish between cognitively normal individuals and patients with Alzheimer's disease dementia in both cerebrospinal fluid and blood.

## Development of the HISCL MTBR-tau243 Reagent



Established the world's first automated immunoassay system for MTBR-tau243



Citation/Adaptation: Murskam, S., et al. (2025). "Development of MTBR-tau Fragment Assay Using a Fully Automated Immunoassay System." CTAD.

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This relates to the performance of the reagent for MTBR-tau243. Although the data for performance evaluation by mass spectrometry are not yet ready in time, we have completed a reagent that does not react with very closely related similar species and reacts only to the measured MTBR-tau. For this as well, we have developed a reagent that can clearly distinguish between the healthy group and patients with Alzheimer's disease in cerebrospinal fluid and blood.

With regard to this, we reported it at CTAD last year, and we are currently receiving interest from various research institutions and pharmaceutical companies.

## Perspective of Technological development for IVD



### 1. Establishing staging detection for preclinical, mid-stage, and late-stage Alzheimer's disease. Promoting market awareness activities aimed at insurance reimbursement

- Preclinical: A $\beta$ 42/40
- Middle : A $\beta$ 42/40 · p-tau217
- Late : p-tau205 · MTBR-Tau243
  - ✓ Demonstrating Sysmex's presence in early and late stages by utilizing A $\beta$ 42/40 and MTBR-Tau243
  - ✓ Differentiation through biomarker paneling
  - ✓ Accelerating development and clinical research with global KOLs
  - ✓ RUO of p-tau217 (FY26 1Q), and early IVD development

### 2. Promote the application of technologies that combine the above markers with previously developed markers (NfL, p-tau181, etc.)

Expanding to other dementias (FTD/DLB) and further applying to non-dementia central nervous system diseases (PD/MS/ALS)

FTD: Frontotemporal Dementia  
DLB: Dementia with Lewy Bodies  
PD: Parkinson's Disease  
MS: Multiple Sclerosis  
ALS: Amyotrophic Lateral Sclerosis

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This is the final slide, and with regard to the future development of technology toward IVD commercialization, we would like to use Alzheimer's disease as the starting point to acquire staging technologies from the preclinical stage to the middle to late stages, and to promote market awareness activities toward insurance reimbursement.

For each layer, as I explained earlier, we will make use of these biomarkers, and we regard A $\beta$ 42/40 and MTBR-tau243 as our proprietary strengths, so we would like to make effective use of these markers and demonstrate our presence. Also, we will advance reagent development and IVD commercialization, taking as one point of differentiation the ability to measure these biomarkers in panel form.

With regard to p-tau217, we are somewhat behind, but early in the fiscal year ending March 31, 2027, we would like to make it RUO and proceed with early IVD commercialization.

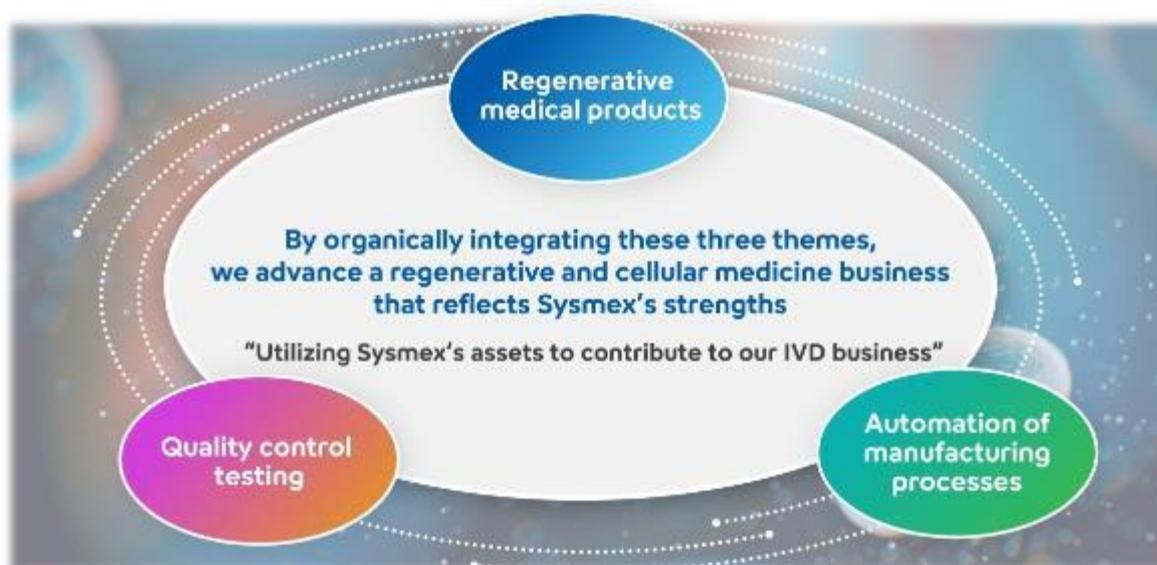
Also, while making effective use of these markers, and in combination with the other markers we have reported to date, we would like to realize blood biomarkers and blood-based diagnostics for other dementias and central nervous system diseases other than dementia.

That concludes my explanation.

Thank you very much.

**Tsujimoto:** I am Tsujimoto of the Next Generation Medical Business Development Division. I would like to introduce our initiatives in regenerative and cellular medicine.

### Three Pillars of the Regenerative and Cellular Medicine Business



With regard to regenerative and cellular medicine, we are advancing three initiatives at Sysmex. One is the development of regenerative medical products, then, on the right, automation of manufacturing processes, and, on the left, quality control testing.

These three are not being pursued independently. Rather, we are moving them forward while integrating the know-how, knowledge, and personal networks gained in each area. Another point, as expressed by being characteristic of Sysmex, is that we are proceeding in a way that fully leverages Sysmex's assets while also contributing to Sysmex's IVD business.

Now then, from this point, I would like to introduce these three initiatives.

## Regenerative Medical Product Pipeline



Promoting the development of regenerative medical products that align closely with our business domains			
Cell type	Target indication	Clinical value	Submission for regulatory approval (expected)
Inducible inhibitory T-cells 	Living donor (liver) transplants	Induction of immune tolerance in recipient T-cells	<b>Around FY2028</b>
iPS cell-derived platelets 	Thrombocytopenia	Restoration of hemostatic function using highly versatile artificial platelets	Around FY2029

\* Cultured hematopoietic stem cells (AlliedCel) are currently being re-evaluated.

First, let me introduce the pipeline of regenerative medical products.

Today, I would like to introduce, in particular, the induced regulatory T cells at the very top.

This cell therapy product is being advanced by AlliedCel, a joint venture established with JCR Pharma, a fellow Kobe-based company, and the intended indication is to enable patients undergoing living donor liver transplantation to take as little immunosuppressant as possible.

In the section on the plan for regulatory filing, it is written in blue text, and compared with our report last year, the situation is slightly delayed. However, this plan was formulated based on the results of the PMDA consultations we have been conducting recently, and we believe this plan is more robust than ever before.

## Environment Surrounding Liver Transplants



Although many liver transplants are performed in Japan,  
the costs and side effects of immunosuppressive therapy remain challenges

Annual number of living-donor liver transplant surgeries (Japan)  
**350–400 cases**

\* Source: Japanese Liver Transplantation Society, "Liver Transplant Registry Report"

Lifetime drug cost for immunosuppressive drugs per patient:  
**Approx. ¥10 million**

\* Estimated by Sysmex based on U.S. market data

Leading causes of death among patients who survived  
one year after liver transplant (Top 2)  
**Malignancy and infection**

\* Rana et al., "Annals of Surgery 2019"

### Malignancy

- Most common cause of death
- Attributed to **increased cancer risk associated with immunosuppression**

### Infection

- Remains a major cause of death even after one year
- **Increased susceptibility to infection associated with immunosuppressive therapy is the main factor**



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As for living donor liver transplantation, about 400 cases are performed domestically, and although engraftment of the patient's liver is maintained over a considerable period, adverse events, as shown at the lower left, are said to be beginning to become apparent.

## Global trends in the reduction and discontinuation of immunosuppressive therapy in organ transplantation



Minimization of immunosuppressive therapy:  
Progress toward establishing a framework for international standardization

### Preparation for international consensus building

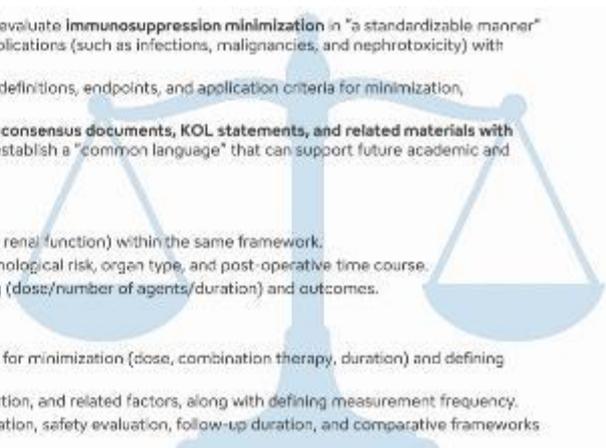
- There is growing international recognition of the need to define and evaluate **immunosuppression minimization** in "a standardizable manner" to balance reduction of long-term immunosuppression-related complications (such as infections, malignancies, and nephrotoxicity) with effective prevention of rejection.
- At **major KOL meetings**, efforts are underway to establish common definitions, endpoints, and application criteria for minimization, **accelerating discussions toward consensus building**.
- The **Japanese Society for Transplantation is also preparing to align consensus documents, KOL statements, and related materials with topics for regulatory consultation and communications**, aiming to establish a "common language" that can support future academic and clinical frameworks.

### Principles of immunosuppression minimization

- **Safety-first:** Evaluate rejection control and safety (infection, tumors, renal function) within the same framework.
- **Risk-stratified:** Clearly define application criteria according to immunological risk, organ type, and post-operative time course.
- **Measurable & reproducible:** Define measurable indicators for dosing (dose/number of agents/duration) and outcomes.

### Collaboration with transplantation societies

- **Development of common definitions:** Harmonizing the terminology for minimization (dose, combination therapy, duration) and defining application criteria.
- **Candidate new endpoints:** Combining rejection, infection, renal function, and related factors, along with defining measurement frequency.
- **Study of standard immunosuppression and adverse event:** Stratification, safety evaluation, follow-up duration, and comparative frameworks



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In light of these results, the term "minimization" has recently been used in academic societies, and there is a movement to reduce the use of immunosuppressants as much as possible. In doing so, while naturally ensuring that organ rejection does not occur, the aim is also to suppress as much as possible the occurrence of adverse events such as those you saw earlier.

Achieving this kind of balance is what will be required going forward with respect to immunosuppressant use in organ transplant patients, and I hope you will understand that the image of the scales on the right represents this balance, and that striking a balance between these two aspects is the future trend.

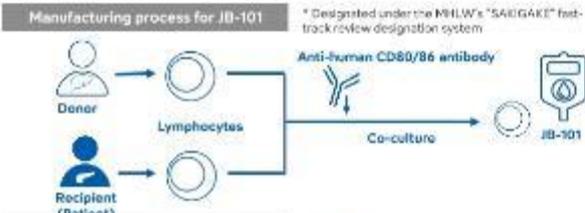
**Inducible inhibitory T-Cells (Investigator-Initiated Clinical Trial Underway)** 

This has the potential to become the world's first cellular therapy to induce sustained immune tolerance in organ transplants, and may also enable the development of tests to monitor immune status

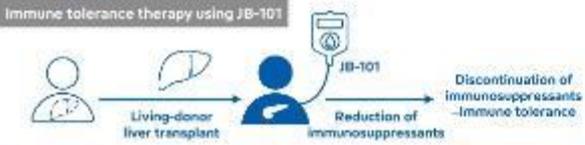
Inducible inhibitory T-cells (JB-101)\* are cells designed to prevent rejection of transplanted donor organs by the patient's immune system

**Manufacturing process for JB-101**

\* Designed under the PMDA's "SAKIGAKE" fast-track review designation system



**Immune tolerance therapy using JB-101**



**Significance of immune tolerance therapy**

- Improved graft survival rate through the induction of immune tolerance
- Reduced risk of complications through reduction or discontinuation of immunosuppressants
- Lower healthcare costs through reduction or discontinuation of immunosuppressants

Immune status monitoring will be key, creating opportunities for our IVD testing technologies

Inducible inhibitory T-cells belong to the same Treg subset as regulatory T-cells recognized by the 2025 Nobel Prize and may attract increasing attention as a therapeutic technology in the future

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We believe that what makes it possible to strike exactly that balance is these Inducible inhibitory T-cells.

This has the code name JB-101, and it is a product created by mixing lymphocytes from the donor patient and lymphocytes from the recipient patient. When this product is administered to the recipient patient, the immune rejection response to the transplanted organ is rendered tolerant, allowing the organ to become established.

As shown in the blue box at the lower right, going forward, immune testing and immune status monitoring will likely become even more necessary than they are now, and as the Sysmex Group at the forefront of developing products like this, we would like to move ahead with the development of new IVD tests.

Also, topics are listed at the very bottom, and this product belongs to the same Treg subset as the regulatory T-cells that received the Nobel Prize last fall. Although Treg-related products are being developed around the world, we believe this may be one of the front-runners.

## Progress of the JB-101 Investigator-Initiated Clinical Trial



Target enrollment: The immunosuppressant dose-reduction period for the 10 enrolled patients has been completed. Future regulatory submission plans are under consideration through prior consultation with PMDA.

### Overview of the investigator-initiated clinical trial led by Juntendo University



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I would like to explain the current status of the clinical trial.

This matter is being advanced as an investigator-initiated clinical trial led by Juntendo University, and it is a clinical trial that has received the Sakigake designation. JB-101, this product, is administered to patients who have been given immunosuppressants, and the immunosuppressants are then gradually reduced. This is a clinical trial in which this is done for 1.5 years, followed by one year of follow-up.

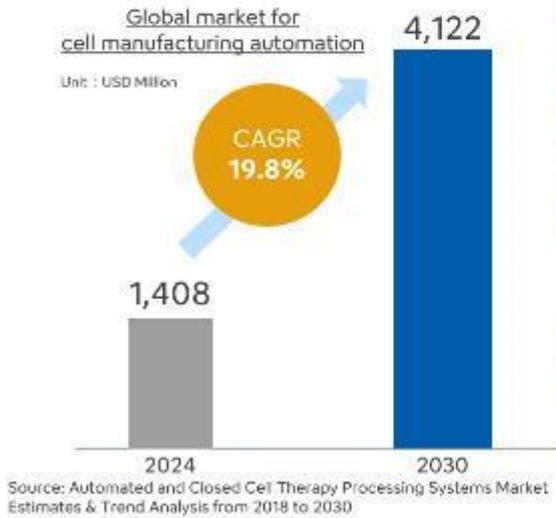
There were 10 enrolled cases, and all have been completed. One case withdrew due to the patient's pre-existing disease, but for the other nine cases, the dose reduction period was completed safely in all cases, and for six cases, the follow-up period has also been completed. For the remaining three cases, the follow-up period will also be completed in the latter half of FY2026, so I believe that at this venue next fiscal year, we may be able to speak in a little more detail.

Then, as for the question of efficacy, today I would like to refrain from discussing that at this point. However, we recognize that we may be obtaining quite promising results, and based on those results, we are currently consulting with the authorities and formulating our regulatory strategy.

# Changes in the Environment Surrounding Regenerative and Cellular Medicine: Automation of Manufacturing Processes



The global market for automation in cell manufacturing is expected to expand, and relevant government agencies are strengthening support



### Manufacturing challenges arising from the use of living cells as raw materials

- Complex manufacturing processes still centered on manual operations drive up costs (labor accounts for approximately 70% of total manufacturing costs)
- IoT adoption remains limited, and data are not centrally managed

### The value of automation is increasingly recognized

- In cell culture processes that rely heavily on manual work and show high variability, robots and AI that provide **reproducibility, precision, and consistency** are highly valued, with some cases being recognized by the FDA as advanced manufacturing technologies

### The government supports manufacturing automation through subsidy programs

- The FY2024 supplementary budget allocated ¥10 billion to newly establish the "Subsidy Program for Investment in Manufacturing Facilities for Regenerative Medicine, Cell Therapy, and Gene Therapy."
- In FY2025, ¥3.9 billion was allocated to the "Fundamental Technology Development Program for the Industrialization of Regenerative Medicine and Gene Therapy."

I would like to introduce the automation of manufacturing processes.

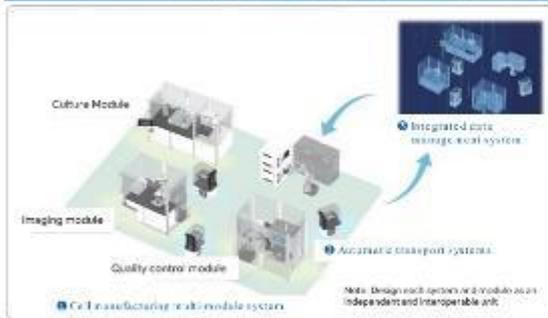
Cell manufacturing is a process that is quite complex, time-consuming, and labor-cost intensive because it involves handling living cells and because people are involved in the process. Put another way, automation is expected to bring about standardized quality in cell manufacturing and optimization of labor costs.

With such expectations in mind, as shown at the lower right, the government is also providing major support through subsidies and the like, and market research reports also indicate, as shown on the left, that this will eventually become a market of USD4 billion.

## Concept of an Automated Cell Manufacturing System



Leveraging our technologies and open innovation with partner companies, we have conceptually designed and completed a prototype of a "modular cell manufacturing system"



- 1 Realization of an automated cell manufacturing system with end-to-end functionality and high versatility through a multi-module system
- 2 Realization of cell and material transport between modules through the adoption of an automated transport system that maintains cleanliness
- 3 Realization of an integrated data management system based on internationally compatible communication protocols and data formats

- Facilitating seamless technology transfer from academia to startups, CDMOs, and pharmaceutical companies
- Allowing manufacturing staff to focus on creative activities while attracting young and cross-disciplinary talent
- Providing safe and effective treatments to patients through stable product quality

Over the past few years, Sysmex has been considering what we can do in this area, and today I would like to introduce the concept we have now arrived at.

It is the modular cell manufacturing system shown in the blue band.

Recently, in cell manufacturing, all-in-one closed systems, in which functions such as culture and centrifugation are incorporated into a single box, have emerged as one trend. However, rather than such an all-in-one system, as you may infer from the expression “modular,” we have arrived at the concept of holding various cell manufacturing functions, such as culture, quality control, and imaging, as modules, so that these modules can be introduced partially or connected when scaling up is desired.

We came to the concept of designing the system flexibly according to each customer's circumstances, such as whether the cell manufacturing site is a large facility or a small facility, or whether the shape is somewhat irregular. By doing so, we believe we can offer benefits such as the possibility of accommodating any kind of customer, from academia to startup companies and pharmaceutical companies, and enabling cell manufacturing staff to shift their work to areas with higher added value.

## Changes in the Environment Surrounding Regenerative and Cellular Medicine: Quality Control Testing



In regenerative and cell therapy, where living cells are used as raw materials, the importance of quality control testing to ensure scientific validation and safety is increasing

In March 2025, the Japanese Society for Regenerative Medicine defined “explorative therapy” and explained its importance

The importance of rapid quality control testing is increasing, and demand for it is growing rapidly



There is a recognized responsibility to **clearly distinguish scientifically validated treatments from those that have not undergone sufficient scientific verification.**

In response to **adverse events and the need to ensure long-term safety**, the Ministry of Health, Labour and Welfare issued the “Guideline on Microbiological Safety of Specified Cell-Processed Products” in October 2025.

### Explorative Therapy

A form of treatment using processed cells, nucleic acids, or other materials that have not obtained marketing approval under the Act on Pharmaceuticals and Medical Devices. Clinical data are accumulated in an independent third-party registry, and **validation studies are conducted before and after treatment.**

The MHLW, FDA, and EMA have issued the **latest guidance supporting the introduction of rapid microbiological testing**

- Technical Guidance on Quality, Non-clinical Studies, and Clinical Studies for Regenerative Medical Products (Human Cell-Processed Products) (June 14, 2016, Yakki No. 0614043)
- USP <1071> Rapid Microbial Methods for Release of Sterile Short-Life Products
- Ph. Eur. 5.1.6 Alternative Methods for Control of Microbiological Quality

Source: Citation from the Japanese Society for Regenerative Medicine, “YOKOHAMA Declaration 2023.”

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Next is quality control.

As for quality control, its importance has been emphasized more and more every year, and as shown on the right, unfortunately, cases of adverse events in patients who received treatment have recently been reported. For this reason, as well, guidelines have been released in which the authorities particularly recommend the introduction of rapid sterility testing, and Sysmex would very much like to contribute to this area as well.

## Deployment of Our Quality Control Testing



Our quality control testing is used across various quality control processes in regenerative and cellular medicine, and our track record continues to expand both domestically and internationally



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Amid these environmental changes, our quality control business is also steadily making progress.

In quality control, as shown in this figure, there are various purposes, such as raw material acceptance testing, in-process testing, and testing before products are shipped. As shown in the photographs, cases of our in vitro diagnostic instruments being used in various stages of cell manufacturing have been accumulating year by year, and recently, we have been receiving inquiries not only from within Japan but also from East Asia, Europe, and the United States.

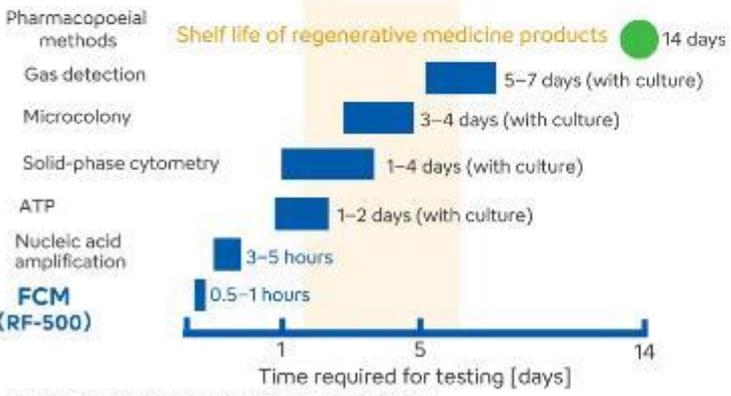
Also, as stated at the very bottom, we are currently conducting a feasibility study while assessing the possibility that some of the tests used here could become in vitro diagnostic reagents.

# Development of Rapid Sterility Testing



Rapid sterility testing using flow cytometry is gaining attention, and we are developing a rapid sterility testing method using our proprietary instruments. After validation with actual samples, commercial launch is planned for FY2026.

## Testing time for rapid sterility testing methods (reference methods)



Source: Arta et al., "Regenerative Therapy," 31,101D43 (2026).

## Key Features of sterility testing using the RF-500

1. Capable of differentiating between live and dead microorganisms
2. Measurement time is one-fifth that of nucleic acid amplification methods
3. When combined with microbial concentration technology, detection sensitivity is equivalent or higher
4. Detects a wider variety of microorganisms than nucleic acid amplification methods

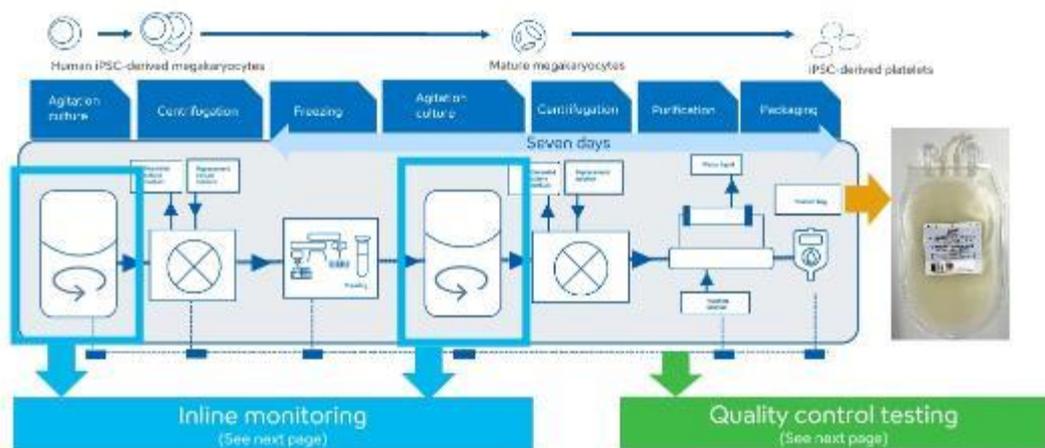
From here are topics in the quality control business. Regarding the rapid sterility test I introduced earlier, as shown at the lower left, our RF-500 flow cytometer is extremely rapid and, as shown in one on the right, has the performance to distinguish live bacteria from dead bacteria, and we have been receiving comments expressing expectations from some stakeholders.

We are still in the process of research and development, but data have been accumulating considerably, and in Fiscal year ending March 31, 2027, although customers may still be limited, we would like to achieve commercialization.

# Example of Our Quality Control Testing in Practice: Megakaryon (1/2)



Systemex technologies are planned to be introduced for process development and quality evaluation in platelet production



Next, I would like to introduce the status of the use of quality control testing in the manufacturing process, based on an example at our subsidiary, Megakaryon.

In the center, we have shown the process for manufacturing iPSC-derived platelets at Megakaryon. On the left are human iPSC-derived megakaryocytes. These are expanded in large numbers, many platelets are produced within the megakaryocytes, and finally, those platelets are released. Platelets are produced through this kind of process.

On the right is a photograph of the actual manufacturing bag. This here is not an imitation at all, but actual iPSC-derived platelets that were produced. Since platelets contain the character for blood, some of you may have thought that the red part was the platelets, but in fact, pure platelets are milky white like this.

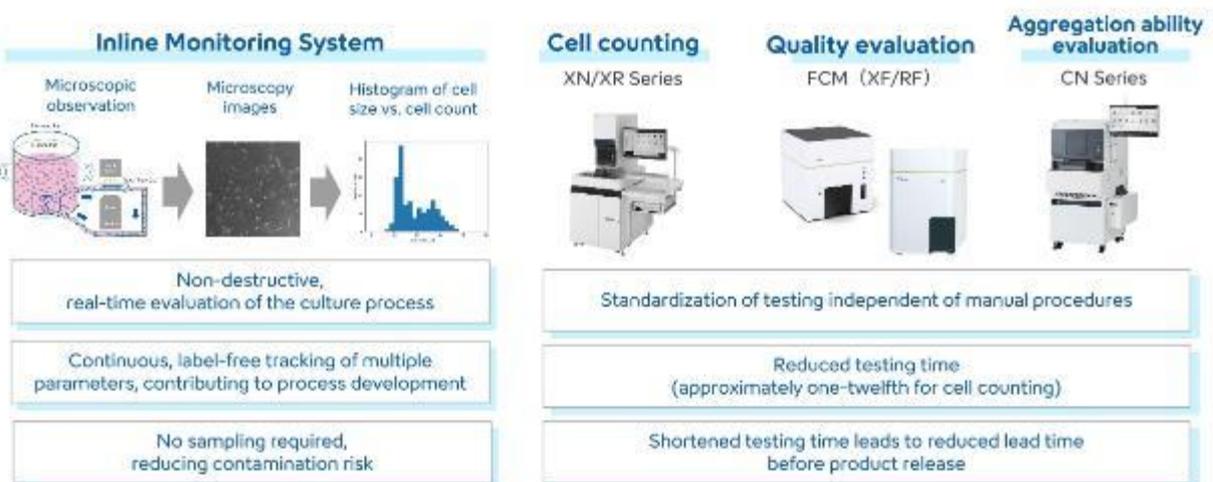
In a sense, this is proof that pure iPSC-derived platelets have been produced, and when you hold it up to the light, the area around the liquid actually sparkles. We have also heard from doctors in transfusion departments that this, too, is proof that pure platelets have been produced, and in this way, I would like you to understand that we already have sufficient technology to produce the platelets themselves.

What remains to be addressed is cost and speed. On these points, Sysmex and Megakaryon are now making steady progress together, and we have gained considerable results and confidence, so we will provide an update again in due course. Thank you very much.

In the manufacturing process at Megakaryon, on the next slide, I would like to introduce two topics related to quality control.

## Example of Our Quality Control Testing in Practice: Megakaryon (2/2)

Fully automated testing instruments developed by Sysmex for its diagnostics business demonstrate value in regenerative and cellular medicine as well, expanding the potential applications of our testing technologies



On the left is an inline monitoring system, which automatically samples the cell culture medium and detects cell morphology and count. This not only reduces labor and eliminates contamination issues, but also has the advantage of making it possible to track the state of cell culture over time.

Also, as shown on the right, our XN/XR-Series, FCM, and CN-Series are playing a major role in the count and function of cells such as megakaryocytes and platelets. Although we are temporarily carrying out development for Megakaryon, by accumulating cases like these, we would like, in a sense, to use them as a showcase to deliver the benefits and value of our quality control to other customers as well.

## Open Innovation



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We believe that initiatives such as these cannot be achieved by us alone, and that open innovation is important. Supported by various companies, Sysmex is advancing regenerative and cellular medicine, and as I stated at the outset, we intend to leverage Sysmex's assets and contribute to Sysmex's IVD business.

That concludes my presentation.

Thank you very much.

[END]