



# Overview of Financial Results for FY2022

**CMIC HOLDINGS Co., Ltd.**  
**November 16, 2022**



# Overview of Financial Results

CMIC GROUP CFO

Wataru Mochizuki





# CMIC Group Network

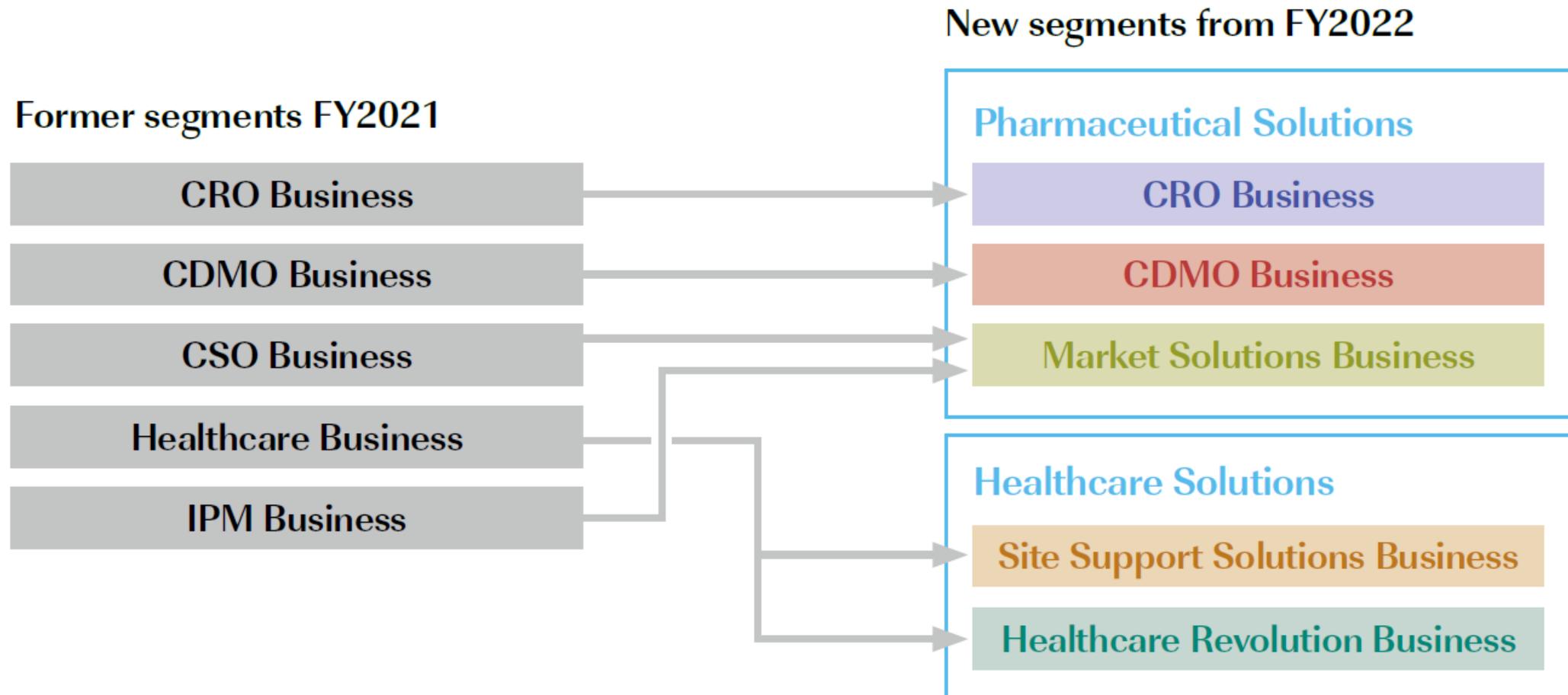


**26 group companies, 62 sites (49 offices, 6 factories, 7 laboratories)**  
**Japan: 13 companies**  
**Overseas: 13 companies**



# Change in reportable segment

From FY22, there will be two reportable segments: Pharmaceutical Solutions, which expands PVC models, and Healthcare Solutions, which contributes to the health of individuals through medical institutions and local governments, etc.



# Focus Activities of Mid-term Management Plan (FY2022-25)

Evolution of healthcare business

Comprehensive support for disease prevention, treatment R&D, and marketing

Contribution to sustainable society through services with high social benefits





## Evolution of healthcare business



- Support for COVID vaccination and PCR testing by local governments • Following up on COVID patients including health observation
  - Utilization of the COVID-19 vaccination information management system “harmo<sup>®</sup> vaccine care”
  - Call center (to consult about adverse reactions), human resources support (Physician and nurse reference, admin staff) , launch of antigen and antibody test kits
- Collaboration with local governments
  - VRS Vaccination Records used by all Citizens: “harmo<sup>®</sup> vaccine care ” in Hokuto City, Yamanashi Prefecture
  - Comprehensive Collaborative Agreement with Myoko City, Niigata Prefecture, on measures against new coronavirus infection and health promotion
  - "harmo<sup>®</sup> vaccine care" app used in seven towns and villages at the foot of Mt. Yotei to prevent accidental vaccination of children
  - Antigen test kits distributed using "drive-through" system in Fujinomiya City, Shizuoka Prefecture

### ➤ Deployment of "Selcheck®" self-check service

- Contributing to disease prevention and early detection by utilizing IoT, bio-sensing data obtained from wearable devices, and self-sampling tests by mail—
- The launch of test kits to self-check the risks of cervical cancer, chronic kidney disease aggravation, frailty, etc.
- Started a POC (Proof of Concept) for stress check



### ➤ harmo® enhancements

- Electronic Medication Record function –Development for new version (app) release
- Provision of survey information
  - "Survey on Trends and Attitudes toward the COVID Vaccine"
  - "Questionnaire on Medication and Driving"



### ➤ Efforts to utilize PHR (Personal Health Record)

June 2022: Joined "PHR Service Business Association (tentative name)"

Study on standardization for effective utilization of data held by various entities related to health and medical care, and development of rules to promote quality improvement of PHR services

Participating companies: A total of 15 companies in the PHR service business (SOMPO Holdings, KDDI, Eisai, Shionogi, Omron, Welby, MICIN, etc.)



CMIC, as coordinator of "Subcommittee 2", will address issues related to standardization and portability of information handled in PHRs.

# Actual Results for FY2022

## Comprehensive support for disease prevention, treatment R&D, and marketing

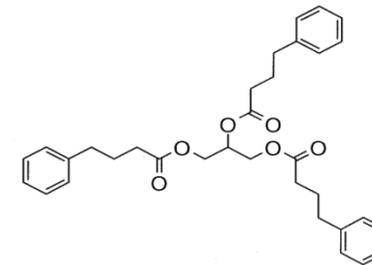


- Accelerating & streamlining drug and device development
  - Partnership with Science 37<sup>®</sup> to accelerate Decentralized Clinical Trials (DCTs) and speed up drug development
  - Increase in trials partially incorporating DCT (telemedicine, home nursing, ePRO, etc.)

- In the bioanalysis business, CMIC supports drug discovery in cutting-edge areas where modalities are diversifying, such as next-generation biopharmaceuticals and gene therapy drugs
- Launched the development of glycerol phenylbutyrate (overseas trade name: Ravicti®) for the treatment of urea cycle disorders in Japan

## \*Urea Cycle Disorders (UCD)

A congenital deficiency of an enzyme in the urea cycle of the liver results in hyperammonemia, a failure to metabolize ammonia



- Best CRO Award (Pharma Intelligence Award 2022)  
Contribution to the approval and launch of pharmaceutical products,  
activities to combat Covid-19, partnerships with several companies,  
and other multifaceted business activities that resulted in a significant increase in  
profit.



# Actual Results for FY2022

## Contribution to sustainable society through services with high social benefits

- CMIC acquires "Kurumin Certification" as a company that supports child-rearing
- Presentation of the 18th "Society Prize (CMIC Prize) of the AIDS Society of Japan" and co-sponsorship of the 13th "International Children's Drawing Contest
- Support of Rare Disease Day (the world rare and intractable disease day) activities
- Support for athletes with disabilities



# Consolidated income statement (overview)



	FY2021		FY2022		Change	Percent Change
	Amount	Composition ratio	Amount	Composition ratio		
	(¥ millions)	(%)	(¥ millions)	(%)		
<b>Sales</b>	85,788	100.0	<b>108,461</b>	100.0	+22,672	+26.4
<b>Operating income</b>	4,920	5.7	<b>11,845</b>	10.9	+6,924	+140.7
<b>Ordinary income</b>	5,091	5.9	<b>13,450</b>	12.4	+8,358	+164.2
<b>Profit attributable to owners of parent</b>	2,023	2.4	<b>8,387</b>	7.7	+6,364	+314.5
<b>Earnings per share</b>	¥111.85		¥469.44			

The situation in Ukraine had no significant direct impact on the Group during the period under review.

# Breakdown of Non-operating income and expenses/Extraordinary income and losses/Income taxes/Profit (loss) attributable to non-controlling interests



(¥ millions)	FY2021	FY2022
Non-operating income	399	1,830
Interest income	2	3
Foreign exchange gains	190	1,720
Share of profit of entities accounted for using equity method	20	—
Other	187	106
Non-operating expenses	228	225
Interest expenses	133	152
Commission fee	19	29
Other	76	43

(¥ millions)	FY2021	FY2022
Extraordinary income	714	139
Gain on sales of investment securities	577	—
Gain on sales of shares of subsidiaries and associates	19	—
Gain on forgiveness of debts	117	—
Gain on reversal of loss of asset retirement obligations	—	139
Extraordinary losses	2,331	1,550
Impairment loss	2,102	1,386
Loss on retirement of non-current assets	107	155
Loss on valuation of investment securities	122	8
Income taxes	2,397	2,994
Current	3,947	6,066
Deferred	(1,550)	(3,071)
Profit attributable to non-controlling interests	(946)	657

# Sales & Operating income by reportable segment



		FY2021 Amount (¥ millions)	FY2022 Amount (¥ millions)	Change (¥ millions)	Percent change (%)
<b>Pharmaceutical Solutions</b>	Sales	68,392	<b>78,188</b>	+9,796	+14.3
	Operating income	3,127	<b>4,752</b>	+1,625	+52.0
<b>Healthcare Solutions</b>	Sales	17,958	<b>31,007</b>	+13,048	+72.7
	Operating income	3,159	<b>8,660</b>	+5,500	+174.1
<b>Adjustments</b>	Sales	(562)	<b>(735)</b>	(173)	—
	Operating income	(1,365)	<b>(1,566)</b>	(201)	—
<b>Consolidated</b>	Sales	85,788	<b>108,461</b>	+22,672	+26.4
	Operating income	4,920	<b>11,845</b>	+6,924	+140.7

## \*Adjustments

Sales are internal elimination of transactions between reporting segments .

Operating income represents corporate expenses that are not allocated to each reportable segment and are related to the Company (holding company).

# Orders received / Backlog

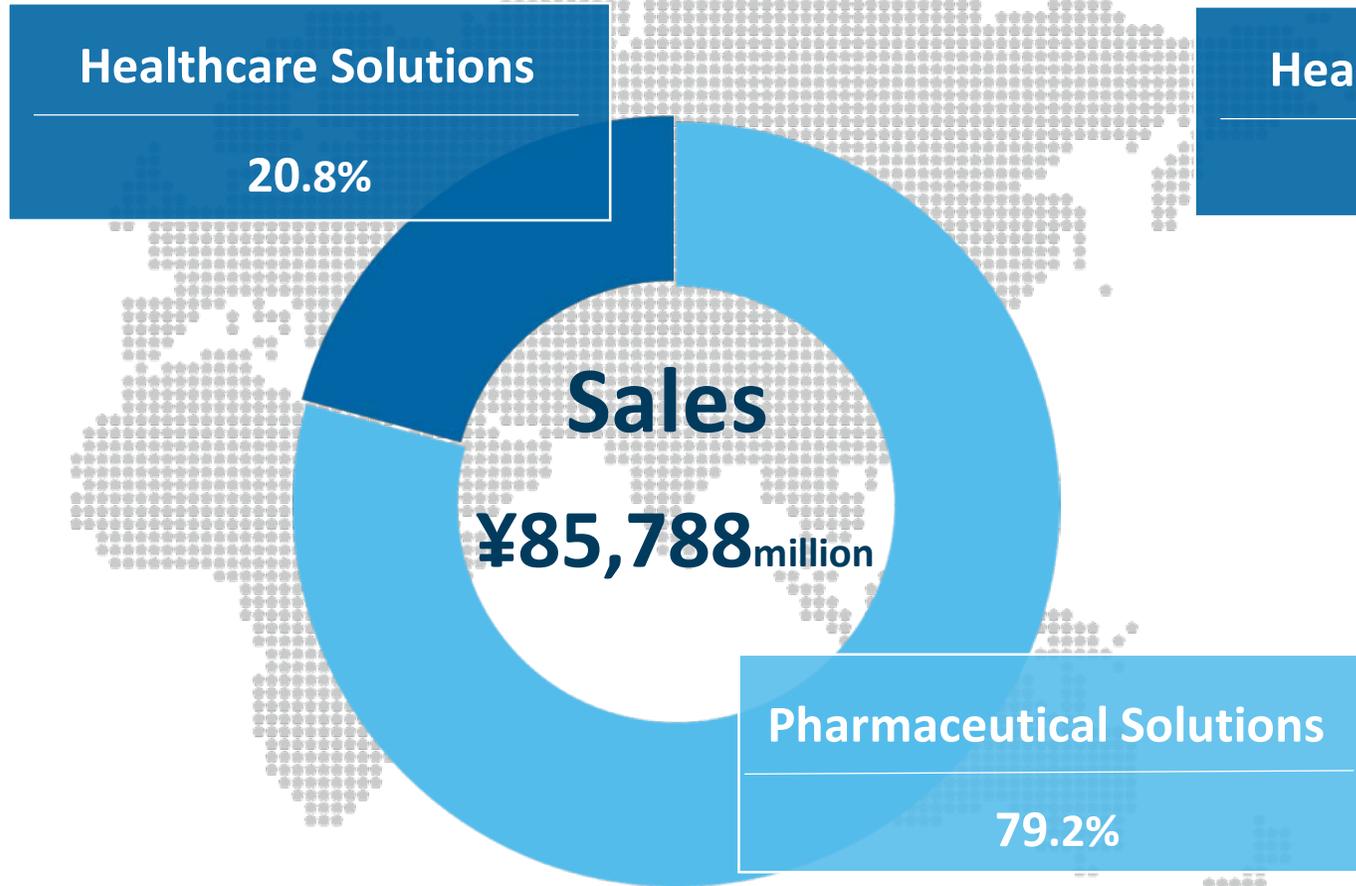


	FY2021		FY2022			
	Orders received	Backlog	Orders received	Percent Change	Backlog	Percent Change
	(¥ millions)	(¥ millions)	(¥ millions)	(%)	(¥ millions)	(%)
Pharmaceutical Solutions	67,851	68,338	<b>80,907</b>	+19.2	<b>74,742</b>	+9.4
Healthcare Solutions	22,164	16,581	<b>29,982</b>	+35.3	<b>16,139</b>	(2.7)
T o t a l	90,015	84,920	<b>110,890</b>	+23.2	<b>90,882</b>	+7.0

# Sales composition ratio



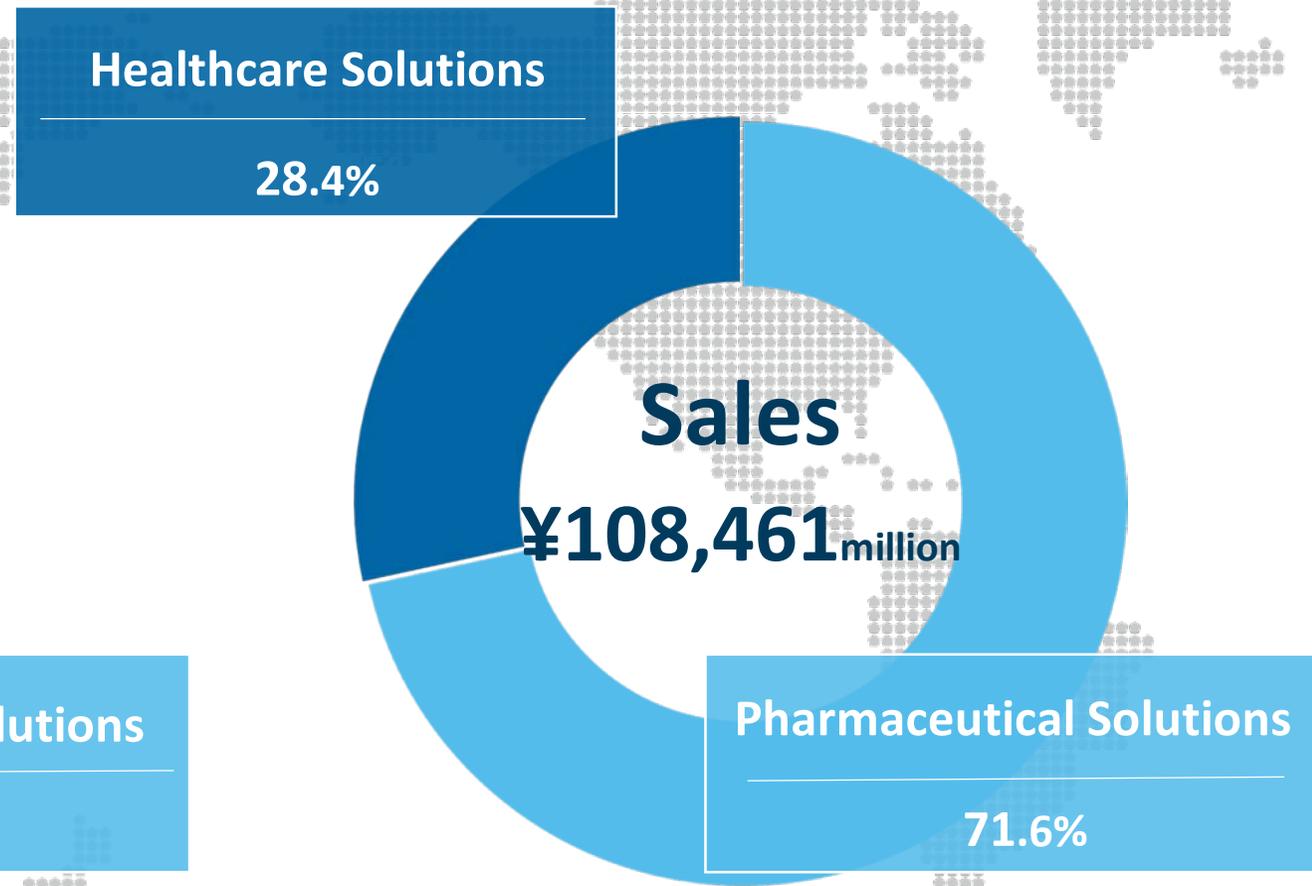
FY2021



Operating income ¥4,920million

Operating margin 5.7%

FY2022



Operating income ¥11,845million

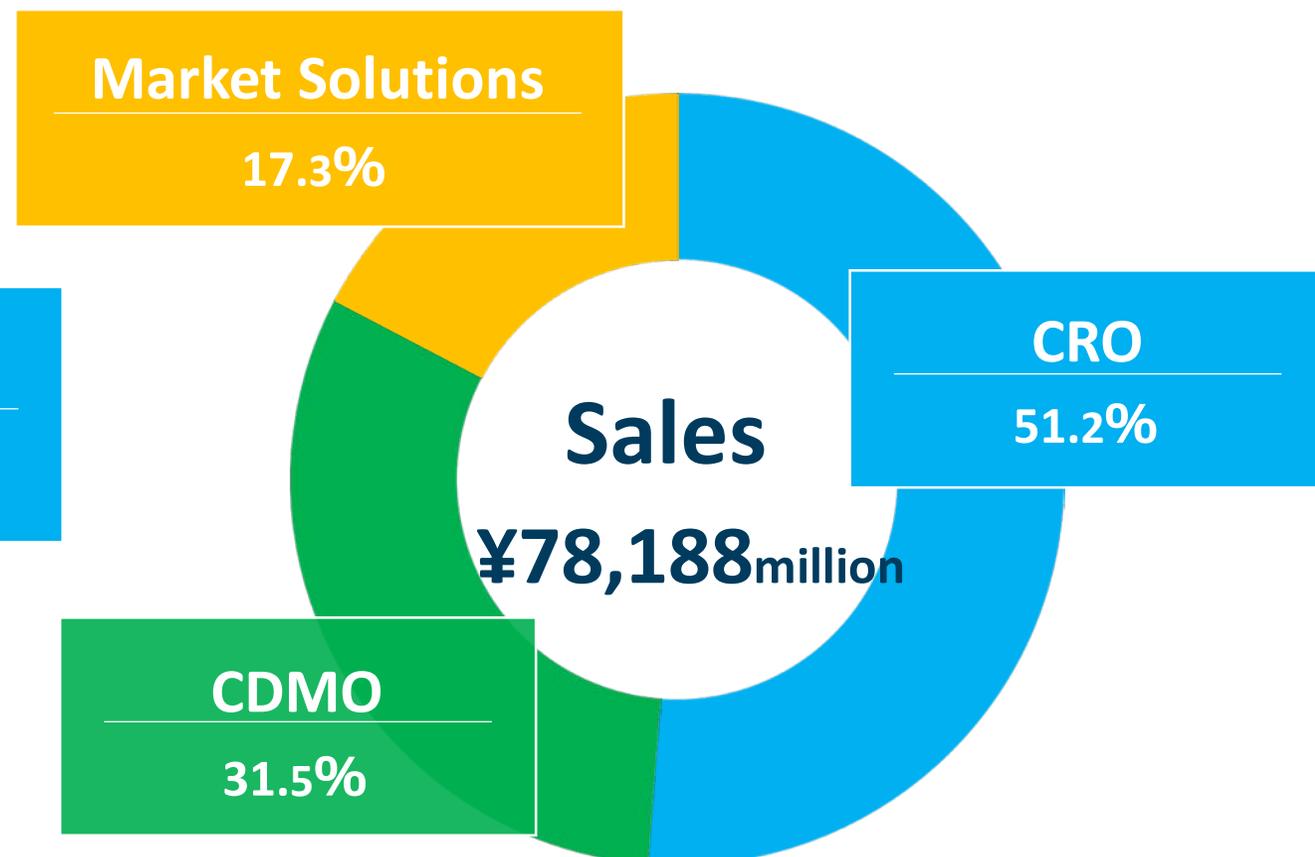
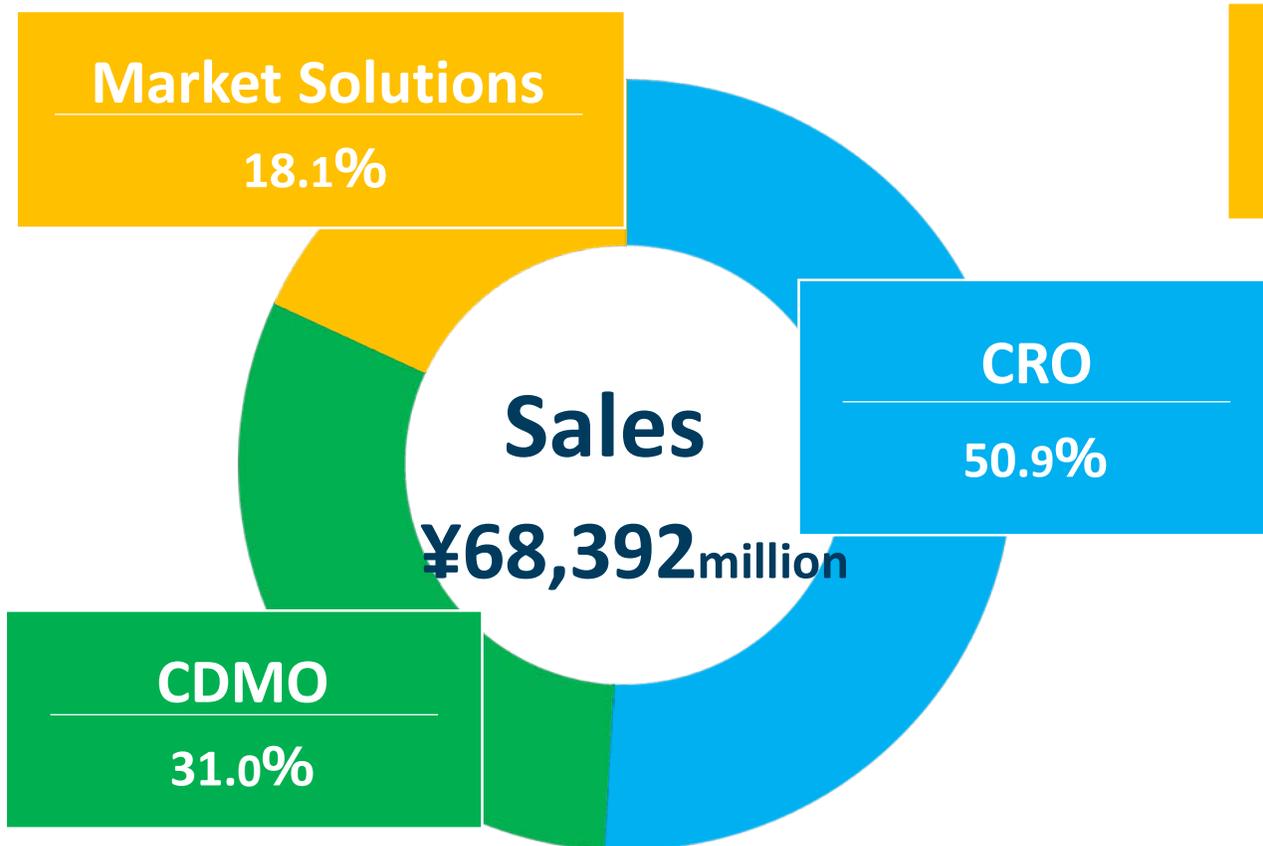
Operating margin 10.9%

# Sales composition ratio of Pharmaceutical Solutions

Pharmaceutical  
Solutions

FY2021

FY2022



Operating income ¥3,127million

Operating margin 4.6%

Operating income ¥4,752million

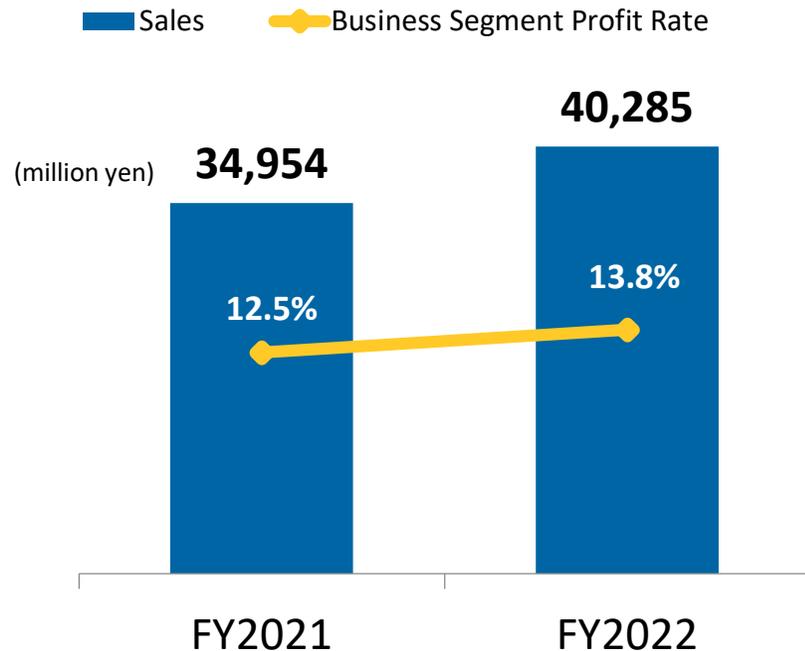
Operating margin 6.1%

# Business Segment: CRO Business

Comprehensive support for research and development of disease prevention and treatment

## Business Overview

- Sales increased from the same period of the previous consolidated fiscal year. Increase in inquiries for development projects
- Partnership with Science 37<sup>®</sup> to Promote Decentralized Clinical Trials (DCTs) and Accelerate Drug Development, Increased number of trials incorporating DCT (telemedicine, home nursing, ePRO, etc.)
- In the bioanalysis business, CMIC supports drug discovery in cutting-edge areas where modalities are diversifying, such as next-generation biopharmaceuticals and gene therapy drugs



## Focus activities

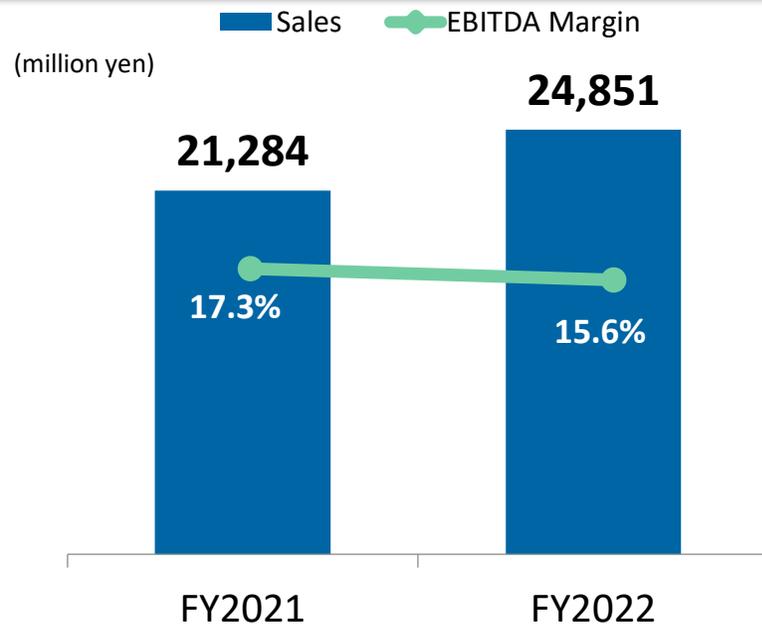
- Enhanced development support for advanced therapies such as biologics and regenerative medicine (full support for filing by Academia and BV)
- Digital applications such as DCT and RWD
- Proactive take on nucleic acid medicine projects via collaboration of laboratories in Japan and the U.S.
- Proactive take on global clinical studies (clinical trials in Asia, Japan-US bioanalysis business)
- Business expansion to the U.S. and Asia
- Aim for the #1 share in Japan

# Business Segment: CDMO Business

Development and manufacturing support for pharmaceutical products and biopharmaceutical API from clinical to commercial

## Business Overview

- Sales increased from the previous consolidated fiscal year
- Growing need to ensure stable supply in response to the spread of new coronavirus infections and generic quality issues
- Responding to supply shortage risks such as rising prices of energy, raw materials, packaging materials, etc., and longer delivery times in manufacturing
- Delayed recovery in US performance, focus on acquiring new projects



## Focus activities

- Steady implementation of production at the Ashikaga injectable facility and its contribution to earnings
- Full-scale development of licensing business for formulation technologies (microneedles, etc.)
- Expand business at the new U.S. site
- Strengthen our position as a strategic partner for domestic pharmaceutical companies

\*Business segment profit (Negative)

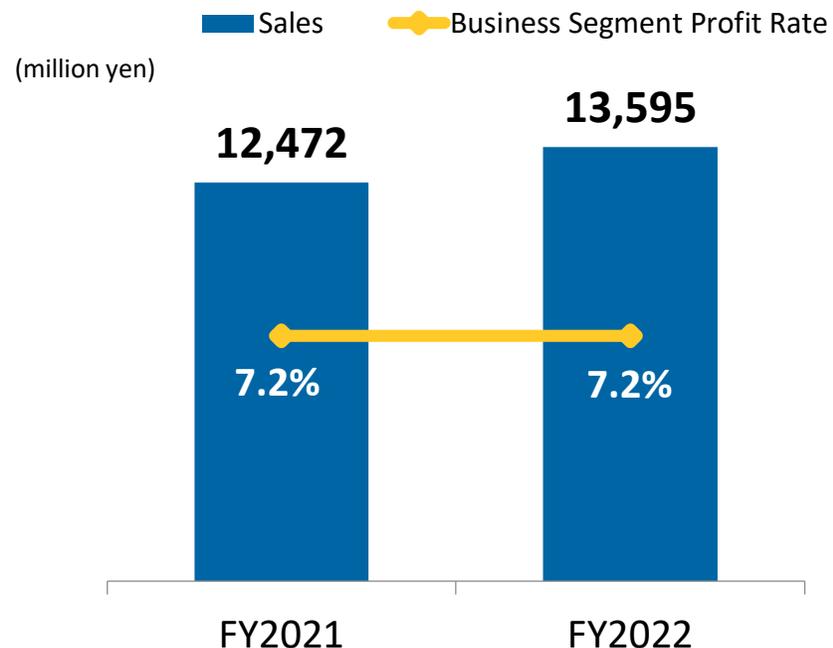
0.3%

# Business Segment: Market Solutions Business

Medical, sales and marketing support for pharmaceuticals, and orphan drugs development to commercialization

## Business Overview

- Sales increased from the previous consolidated fiscal year
- Acquired new projects and made steady progress in existing projects in MR dispatch services
- Launched the development of glycerol phenylbutyrate (overseas trade name Ravicti®) for the treatment of urea cycle disorders in Japan



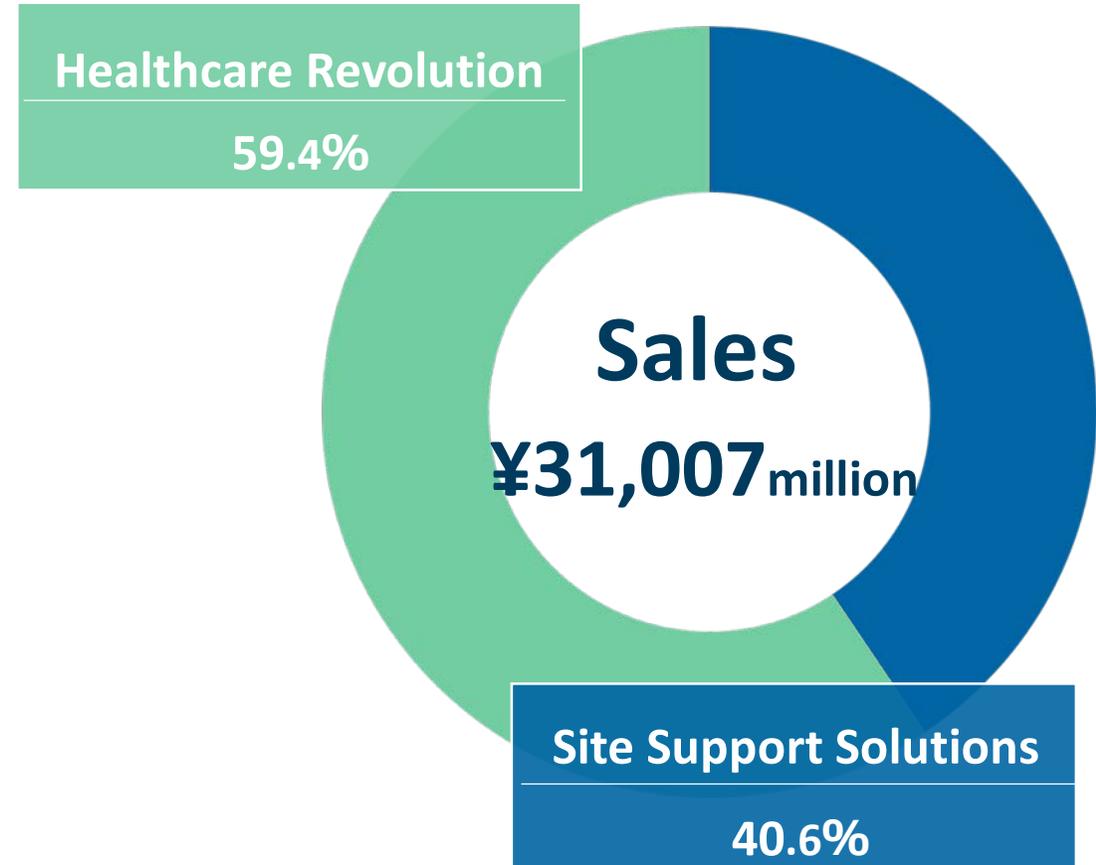
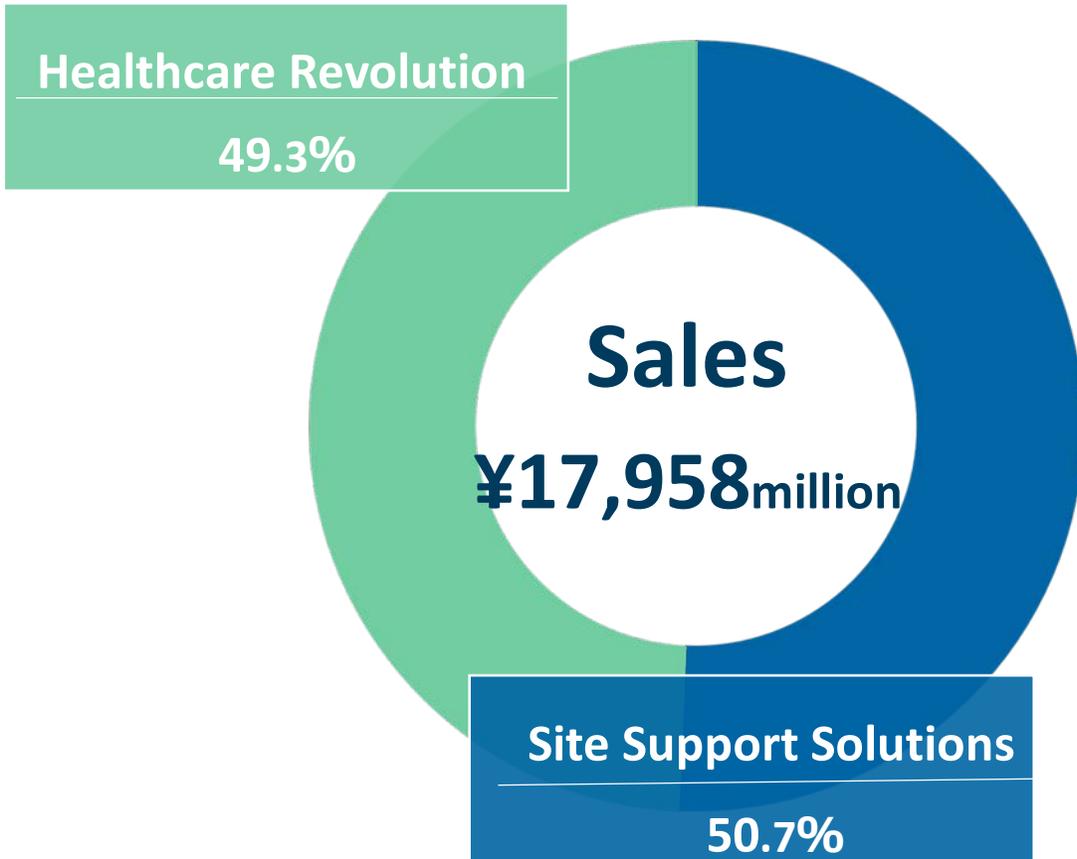
## Focus activities

- Expand positioning in the MR dispatch business
- Efficient recruitment of MRs and MSLs
- Provision of hybrid services
- Promotion of multi-channel
- Development of new orphan drugs
- Supporting foreign pharmaceutical companies entering the Japanese market

# Sales composition ratio of Healthcare Solutions

FY2021

FY2022



Operating income ¥3,159million  
Operating margin 17.6%

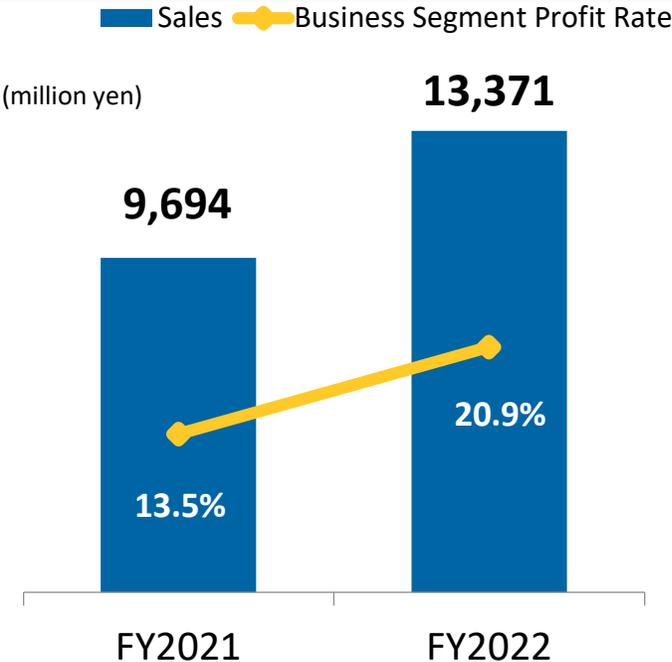
Operating income ¥8,660million  
Operating margin 27.9%

# Business Segment: Site Support Solutions Business

Comprehensive support of medical institutes and medical staff

## Business Overview

- Sales significantly exceeded the previous consolidated fiscal year
- Increase in development projects for vaccines and therapeutic drugs for new coronavirus infections
- Needs for clinical trials (researches) and other support for medical institutions are expanding
- Promote collaboration with academia



## Focus activities

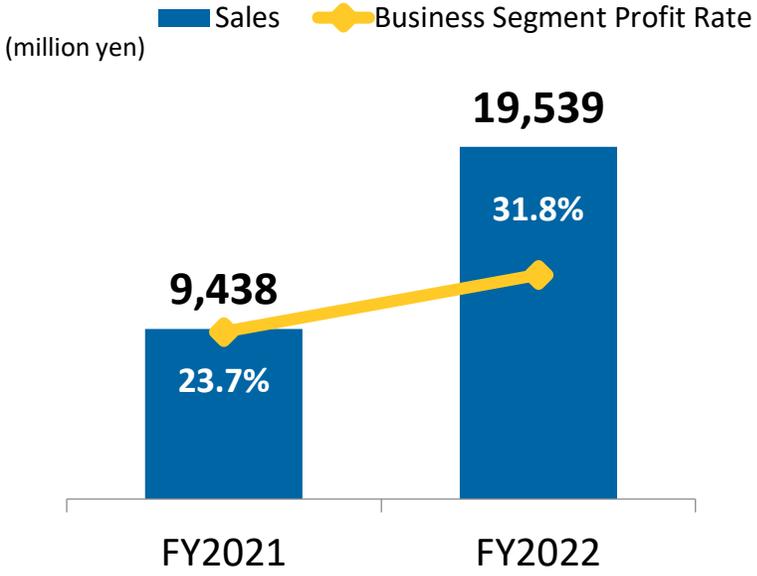
- Shifting from treatment to prevention/prognosis market (prophylaxis treatment agents and clinical trials using apps)
- Providing support for university hospital network, etc.
- Providing services in community healthcare

# Business Segment: Healthcare Revolution Business

Support individuals, local governments, etc. with solutions using a new ecosystem of health care

## Business Overview

- Sales significantly exceeded the previous consolidated fiscal year
- Municipal support services greatly expanded from vaccination support services for new coronavirus infection
- Expansion of businesses that integrate disease prevention, health information, and IT technologies
  - OKEIOS Inc., a developer of data management platforms for healthcare information coordination, became an equity-method affiliate
  - Developing self-testing services such as the launch of the Frailty\* testing kit "FrailSign" and POC (Proof of Concept) for stress check
- Promote the use of harmo® as a Healthcare Communication Channel in PHRs, etc.



## Focus activities

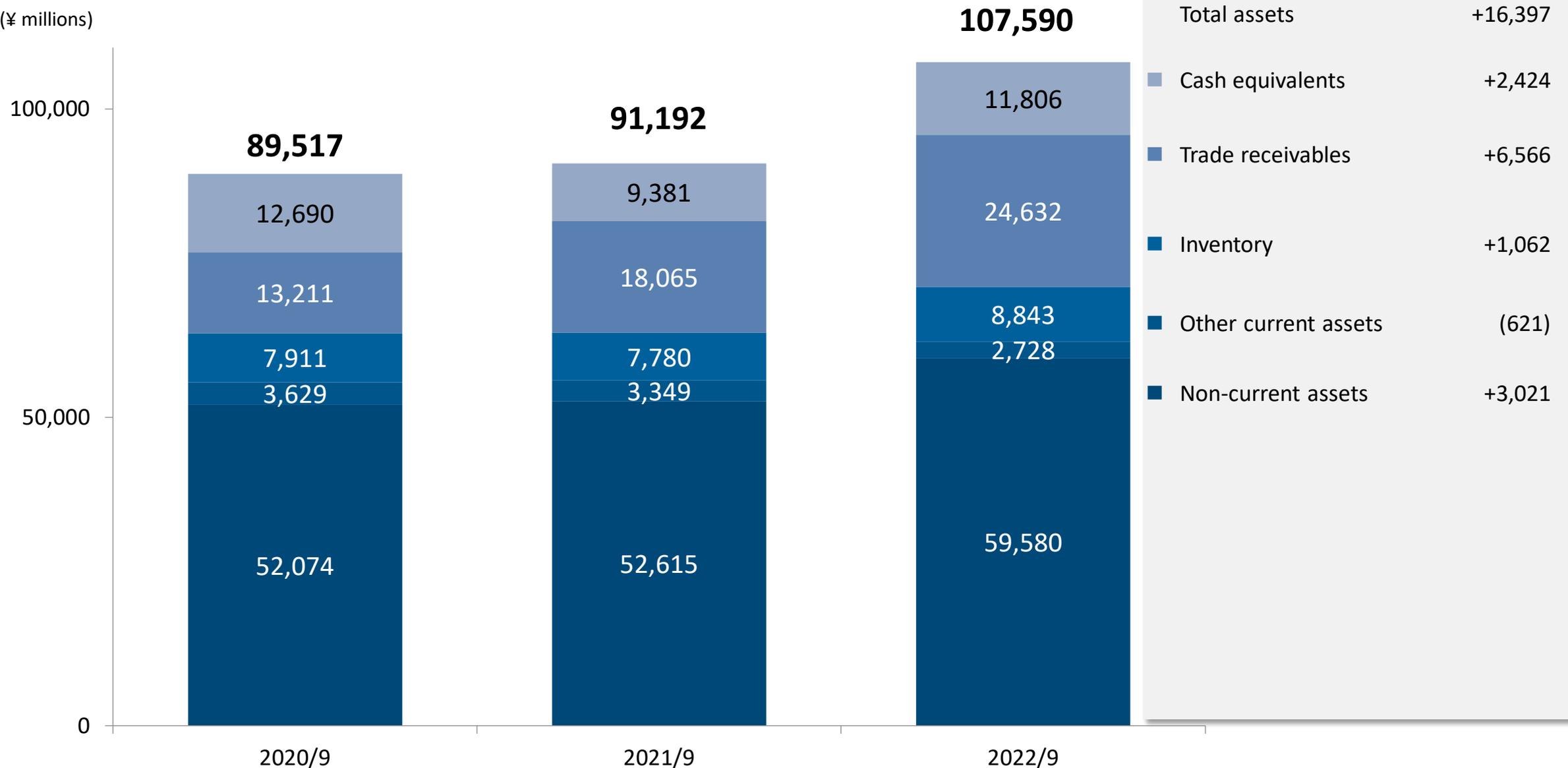
- Expansion of healthcare services & utilization of data by using harmo®
- Expansion of healthcare services for local governments and companies
- Expansion of self-screening services
- Nurture and secure healthcare human resources

\* Frailty : Decline in physical and cognitive functions

# Consolidated balance sheet (assets)



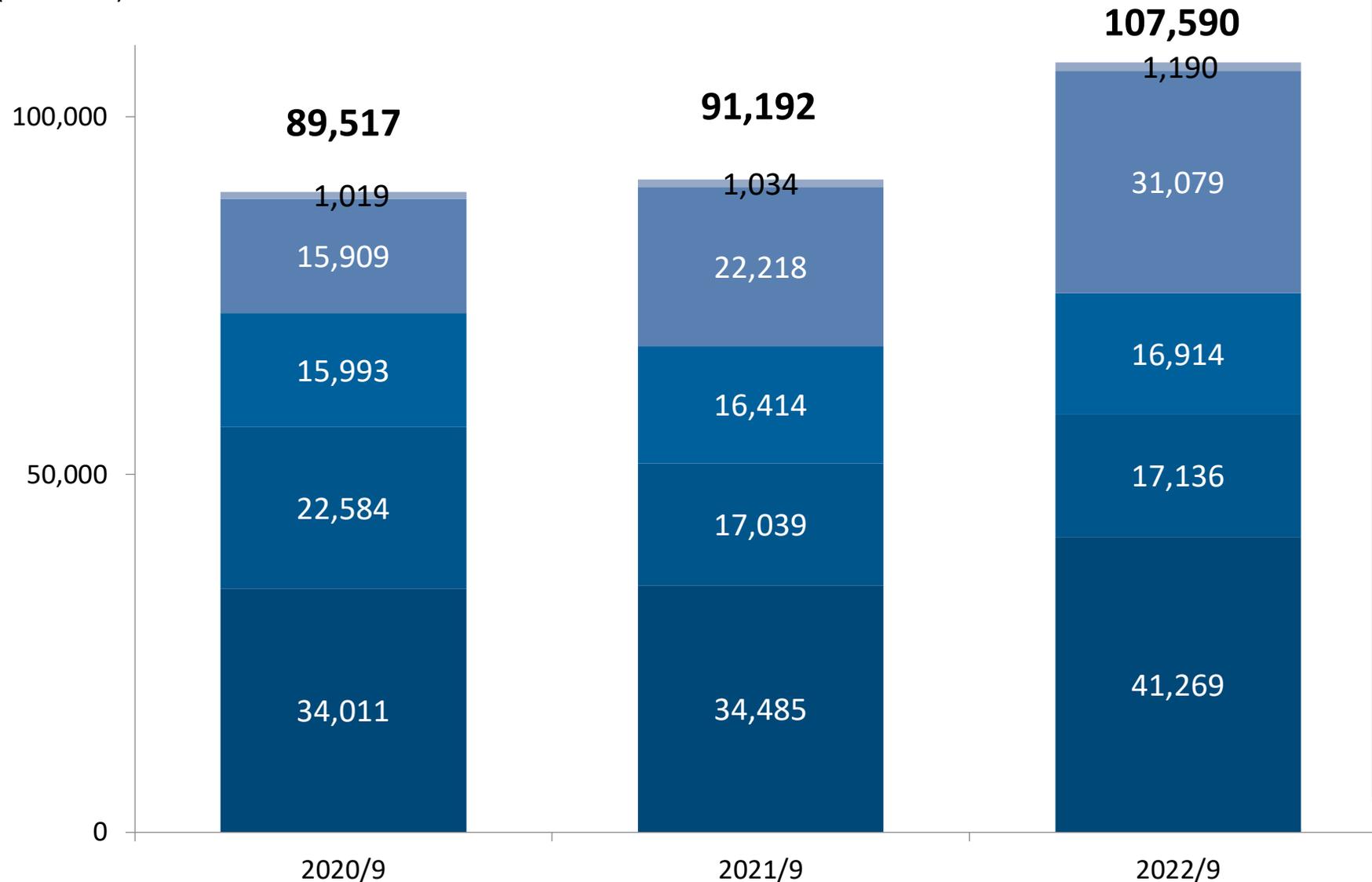
(¥ millions)



# Consolidated balance sheet (liabilities and net assets)



(¥ millions)



Accounts payable	+155
Other current liabilities	+8,861
Other non-current liabilities	+499
Interest-bearing debt (excl. lease obligations)	+97
Net assets	+6,783

# Cash Flows



(¥ millions)	2021/9	2022/9	Increase (decrease)	【Key factors】
Cash flows from operating activities	9,804	11,213	+1,408	(Cash flow from operating activities) • Increase in funds due to recording of income before income taxes, etc.
Cash flows from investing activities	(6,685)	(8,045)	(1,360)	
Cash flows from financing activities	(6,348)	(1,230)	+5,117	(Cash flow from investing activities) • Expenditures for the acquisition of property, plant and equipment, etc. in the CDMO business
Effect of exchange rate change on cash and cash equivalents	(82)	325	+407	
Net increase(decrease) in cash and cash equivalents	(3,310)	2,263	+5,574	(Cash flow from financing activities) • Payment of dividends and purchase of treasury stock, etc.
Increase in cash and cash equivalents resulting from inclusion of subsidiaries in consolidation	1	60	+58	
Cash and cash equivalents at beginning of period	12,688	9,379	(3,308)	
Cash and cash equivalents at end of period	9,379	11,703	+2,323	

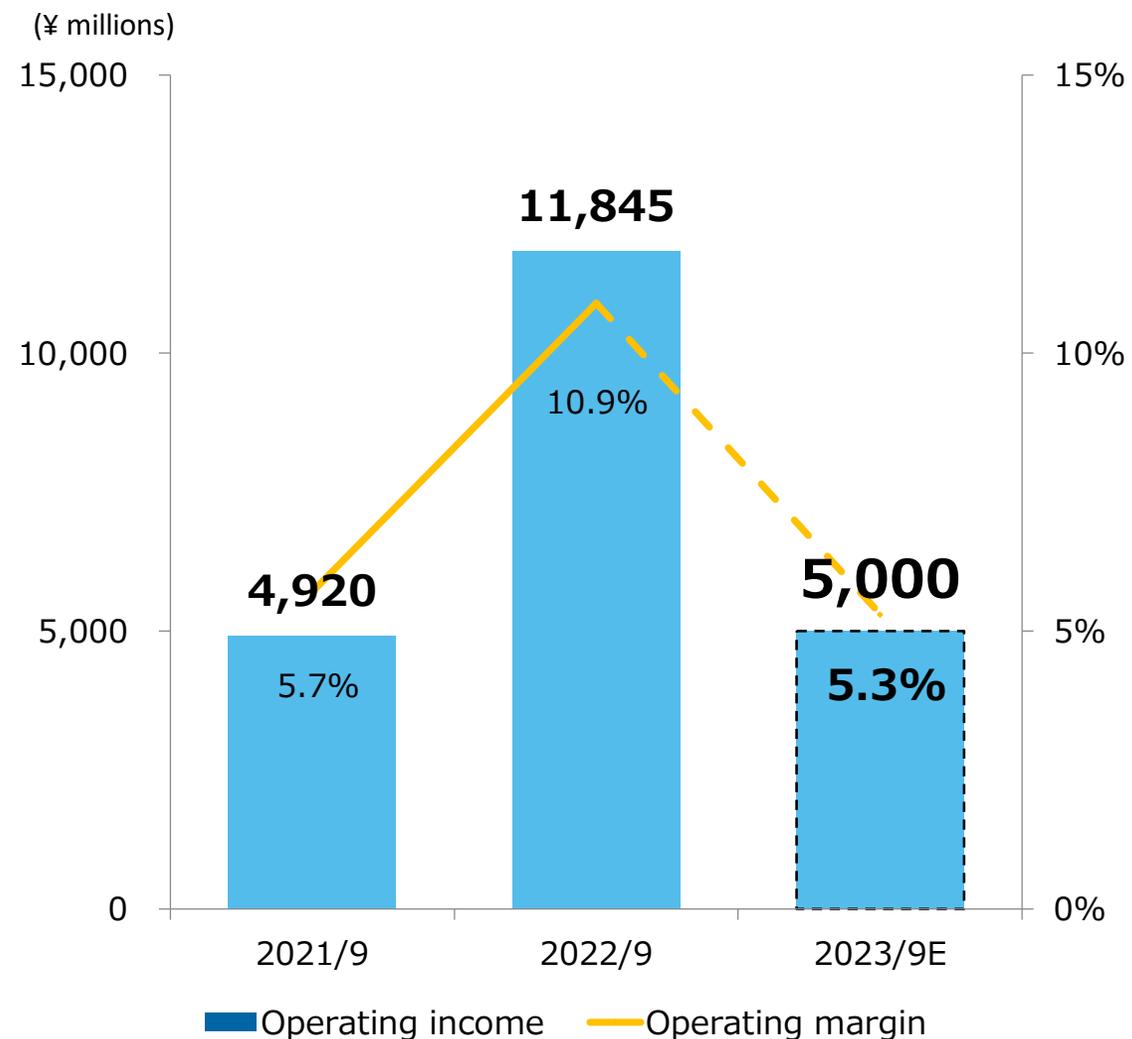


# Forecast for FY ending Sep. 2023

# Forecast for FY ending Sep. 2023



	2022/9 Actual	2023/9 Forecast	Change (%)
	(¥ millions)	(¥ millions)	
Net Sales	108,461	<b>95,000</b>	(12.4)
Operating income	11,845	<b>5,000</b>	(57.8)
Ordinary income	13,450	<b>4,700</b>	(65.1)
Profit attributable to owners of parent	8,387	<b>2,900</b>	(65.4)
Earnings per share	¥469.44	<b>¥163.64</b>	





# Future outlook of CMIC Group's Business

CMIC Group CEO  
Dr. Kazuo Nakamura



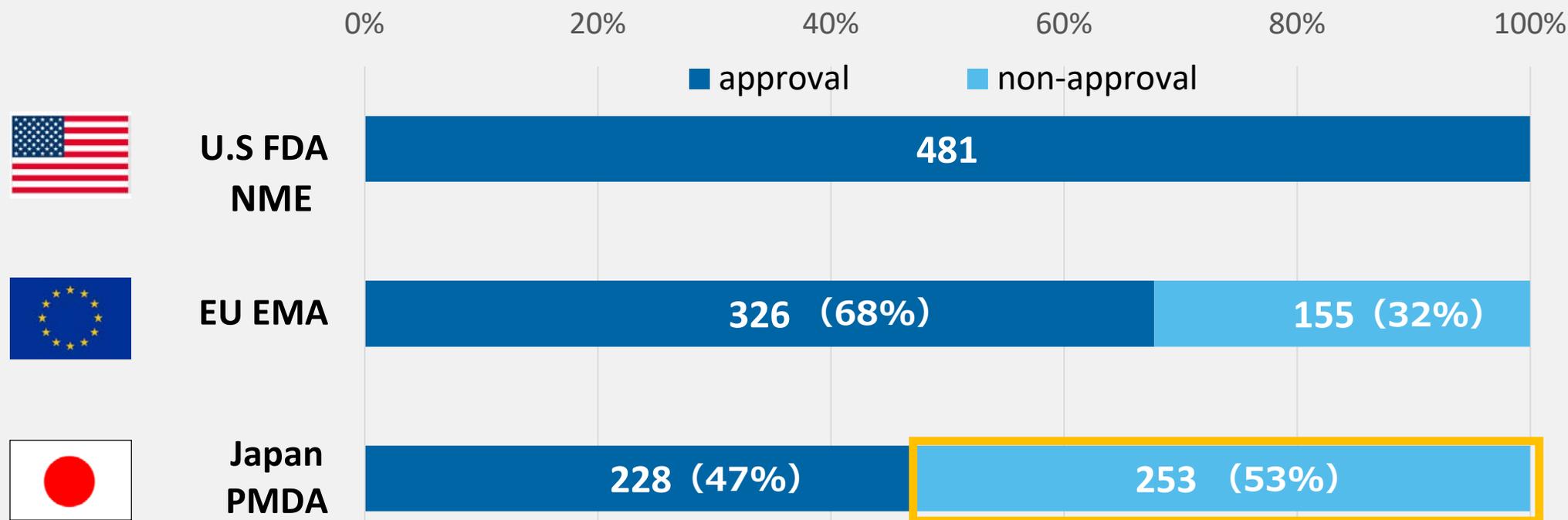


# Changes in New Drug Development

# Japan's drug lag gets worse

The number of "unapproved drugs in Japan" that have already been approved in Europe and the U.S. but not yet approved by Japanese health authority is increasing.

## FDA-approved NMEs in Japan and Europe (481 products from 2010 to 2021)



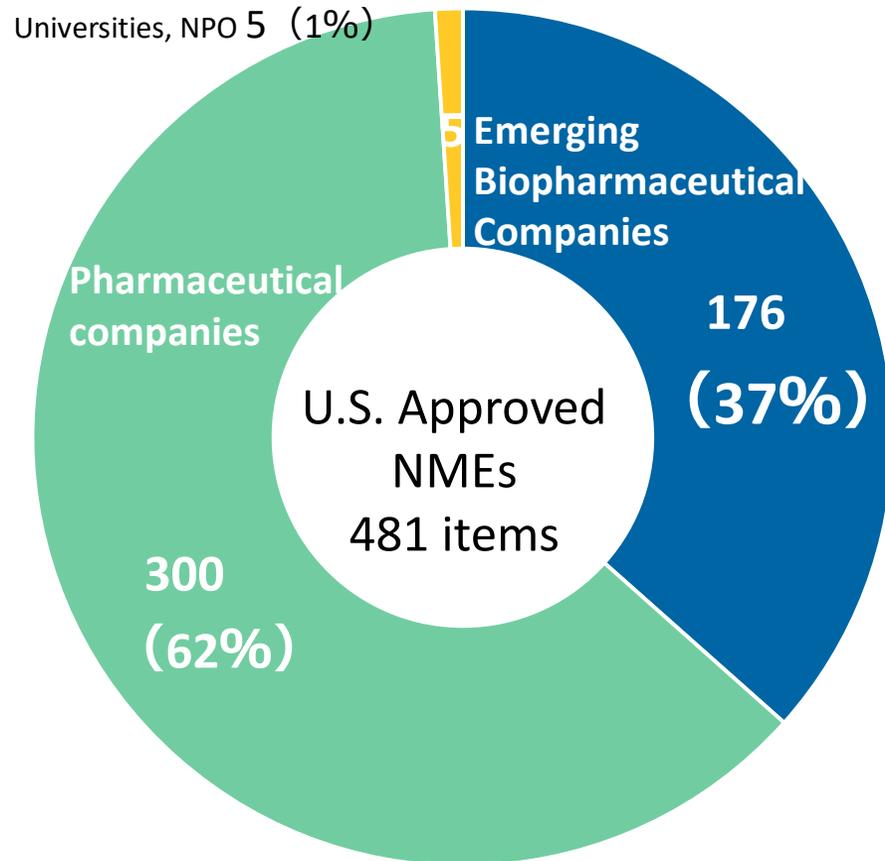
More than half are not approved in Japan

Note: Approval status in Japan and Europe is based on information as of the end of 2021.  
Source: Prepared by OPIR (Office of Pharmaceutical Industry Research) based on publicly available information from the PMDA, FDA, and EMA.  
[https://www.jpma.or.jp/opir/news/067/pdf/67\\_2.pdf](https://www.jpma.or.jp/opir/news/067/pdf/67_2.pdf)

# New drugs from emerging biopharmaceutical companies with low approval rates in Japan



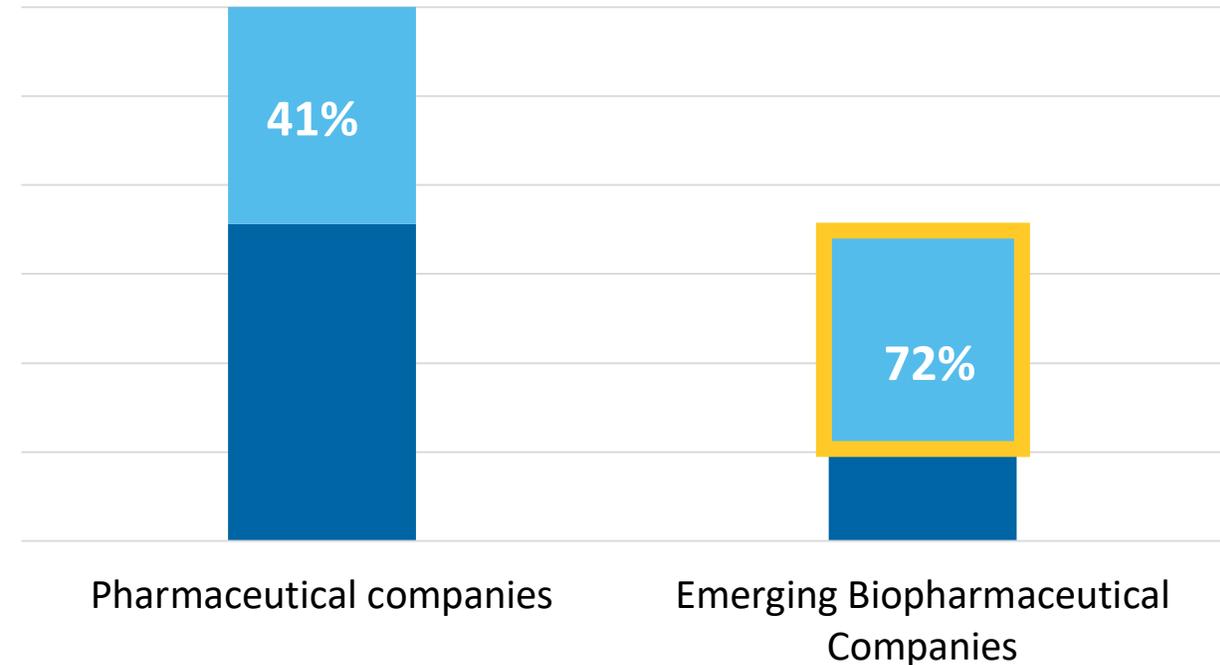
## U.S. NMEs



## Japan approval percentages of US approved NME, classified by the type of pharmaceutical company

Percentage of Approval  
No. of approved products

■ approval ■ non-approval



**70% of new drugs from emerging biopharmaceutical companies are not approved in Japan**

Source: Created by OPIR (Office of Pharmaceutical Industry Research) based on publicly available information from PMDA, FDA, EMA, and EvaluatePharma  
[https://www.jpma.or.jp/opir/news/067/pdf/67\\_2.pdf](https://www.jpma.or.jp/opir/news/067/pdf/67_2.pdf)

**Urgent need to create an environment for expansion in Japan**

# Changes in Drug Development in the Japanese Market



Japan is attracting renewed attention because of its ability to conduct high-quality clinical trials at reasonable development costs.

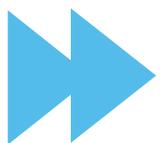
For example,

## Emerging biopharmaceutical companies from overseas

No Japanese subsidiary and no foothold in drug development; therefore, high need for In-Country Clinical Caretaker (ICCC) and regulatory affairs consultation to support new drug development in Japan

## Domestic pharmaceutical companies

COVID pandemic has made it difficult to import and export overseas, increasing the need for local production and support for overseas expansion.



**Established the "Consulting and Navigation Unit," an organization of consultants with a wealth of experience and a high level of expertise.**



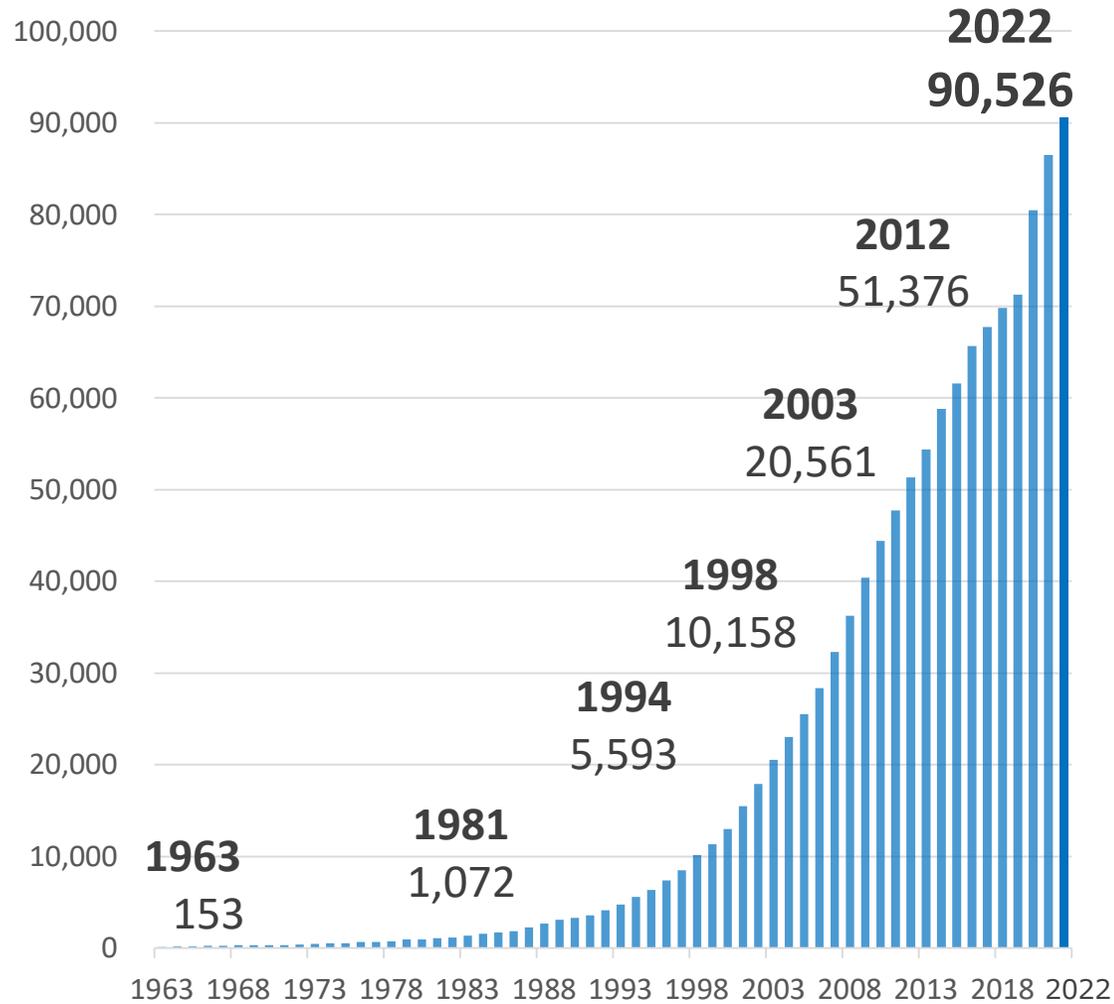
# "IKIGAI"

## Agenda of super aging society

# Japan's aging population

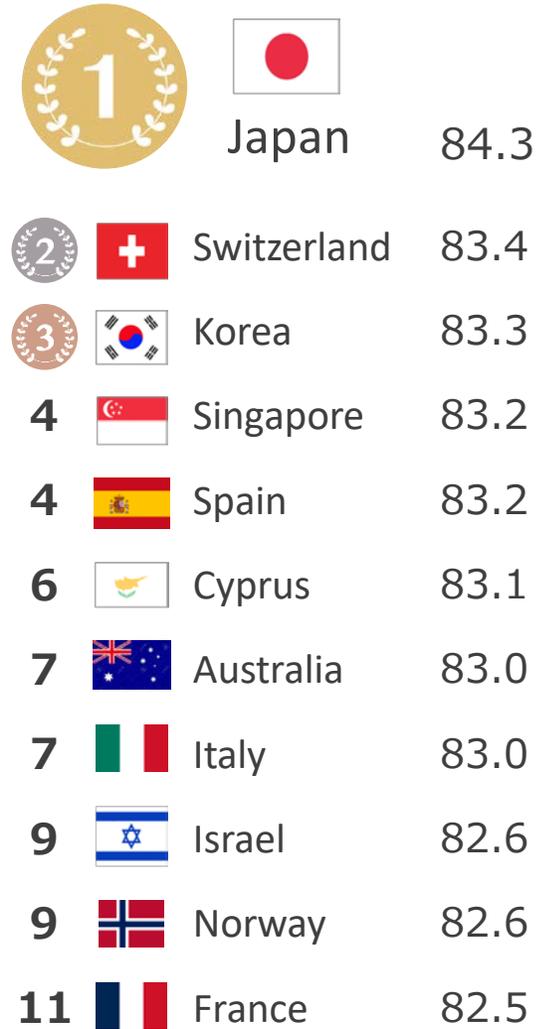


## Increasing no. of people aged 100 or older

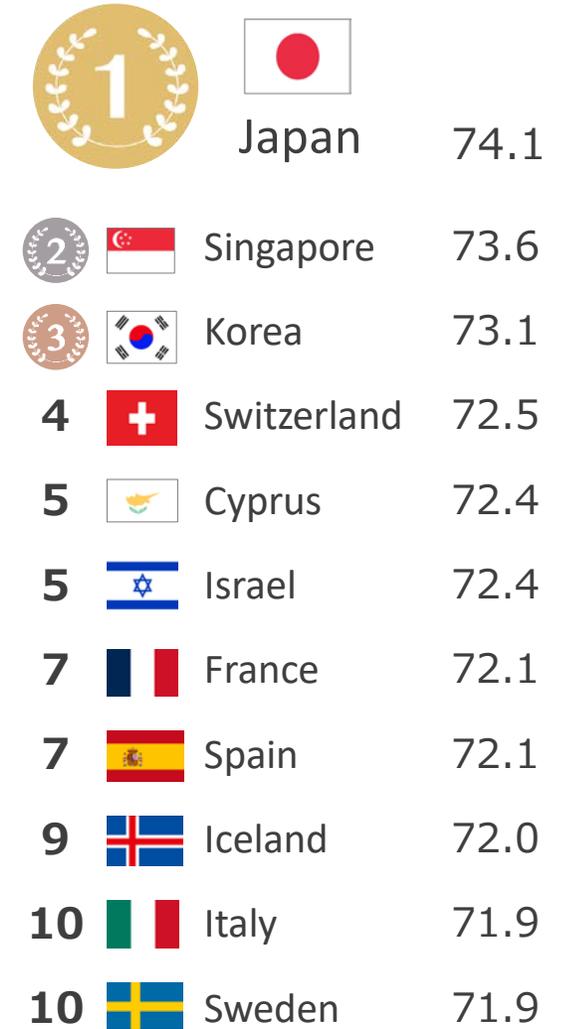


Source: MHLW

## Average life-span

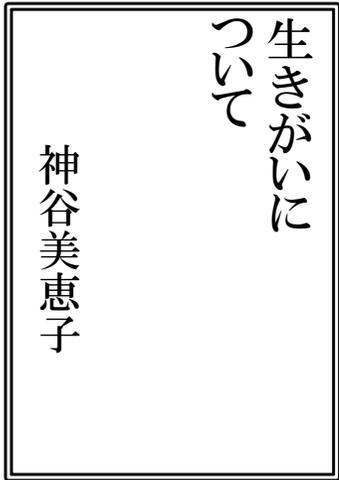


## Healthy life-span

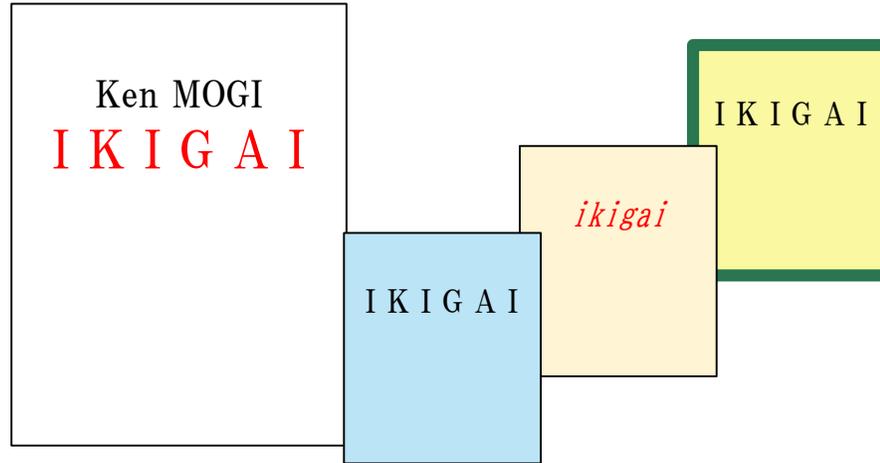


Source : WHO World health statistics 2022

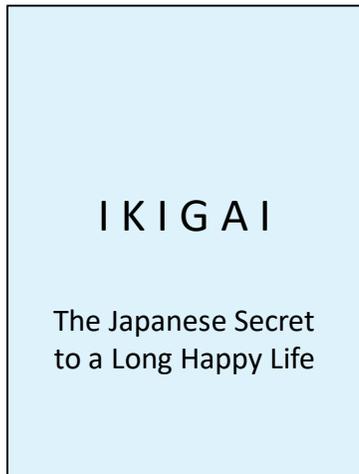
# What is "IKIGAI"



A book published in 1966  
Bestseller over the years,  
still read by many people



A global bestseller books on "IKIGAI"  
Became a hot topic in 31 countries

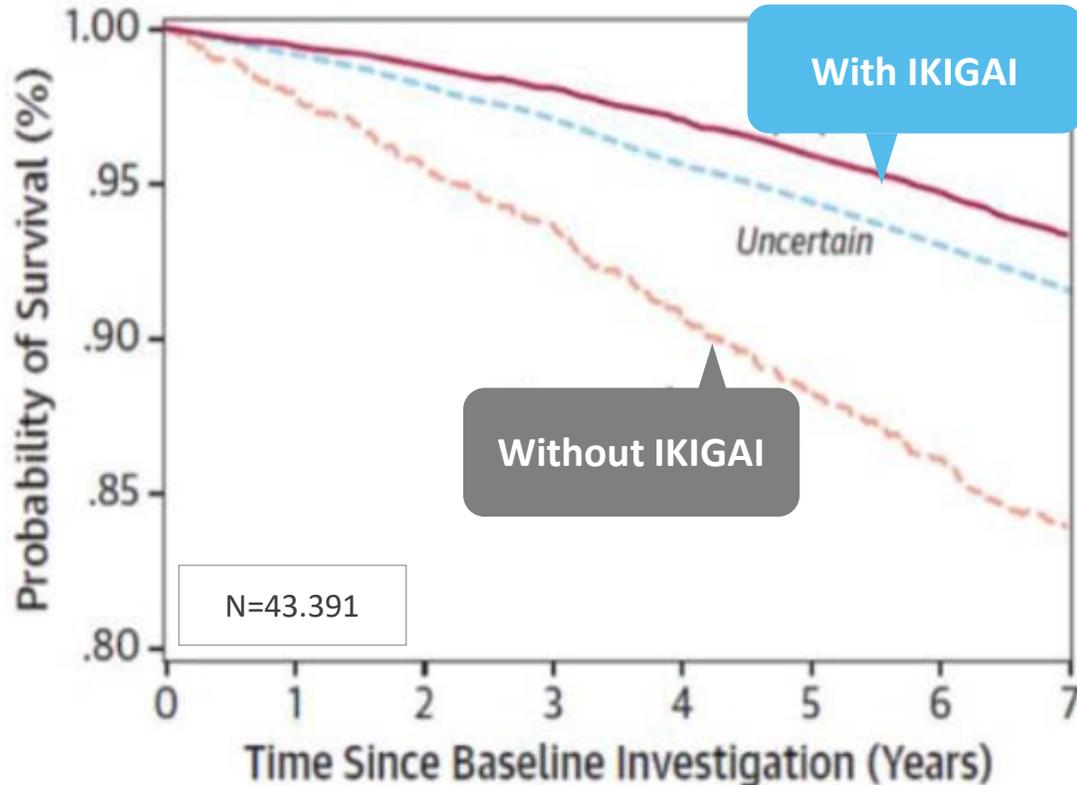


Spanish book published in Spring 2016  
Translated into 63 languages and became an  
international bestseller



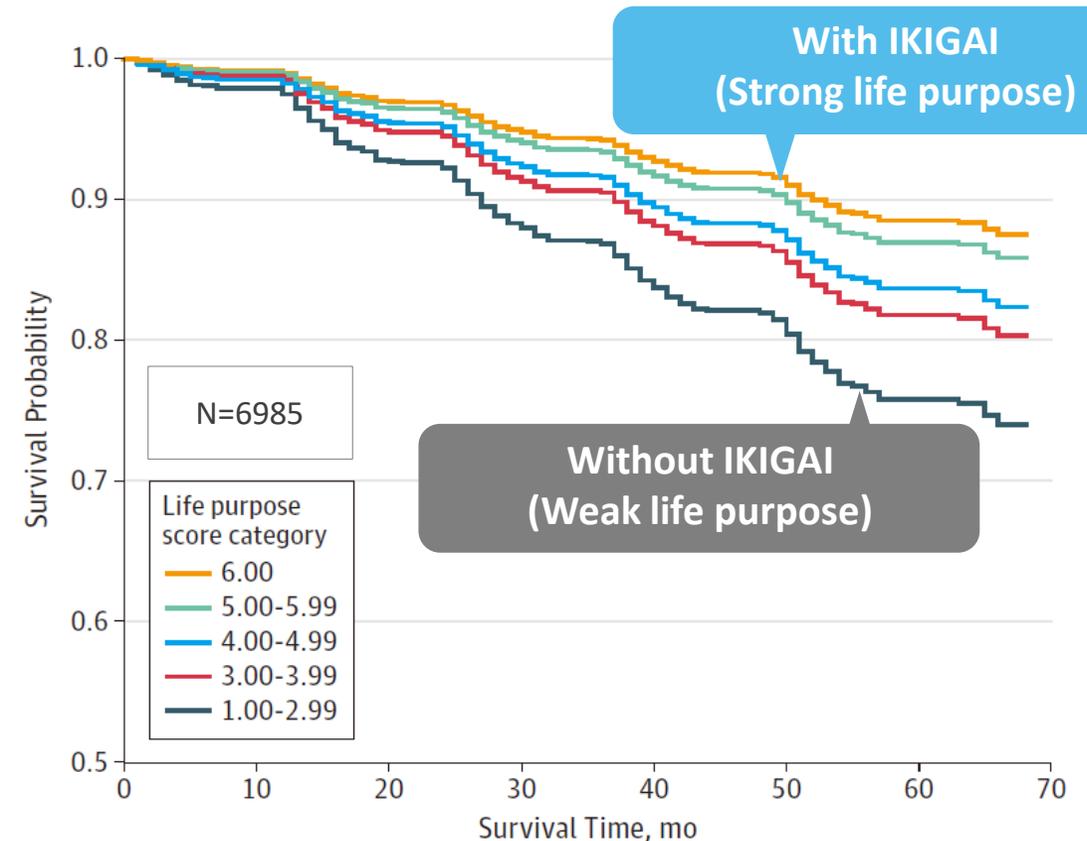
# Effects of “IKIGAI” on health

“IKIGAI” is proven to be related to healthy longevity



Division of Epidemiology, School of Public Health, Tohoku University Graduate School of Medicine, "Sense of Life Worth Living (Ikigai) and Mortality in Japan: Ohsaki Study", The Ohsaki Study, a prospective cohort study 2008

Figure: Survival Curves Illustrating the Association between Life Purpose and Mortality



JAMA Network Open. 2019;2(5):e194270. doi:10.1001/jamanetworkopen.2019.4270

Aliya Alimujiang, MPH; Ashley Wiensch, MPH; Jonathan Boss, MS; Nancy L. Fleischer, PhD, MPH; Alison M. Mondul, PhD, MPH; Karen McLean, MD, PhD; Bhramar Mukherjee, PhD; Celeste Leigh Pearce, PhD, MPH

This suggests “people who have IKIGAI tend to live longer”.

# Harvard University, 75-year follow-up study (Grant and Glueck Study)



It turns out that “good human relationships” are more involved in longevity than cholesterol levels, blood pressure, and blood sugar levels.

“The surprising finding is that **our relationships and how happy we are in our relationships** has a **powerful influence on our health**”

”Those who kept warm relationships got to live longer and happier, and the loners often died earlier.“

“**Loneliness kills,**  
it’s as powerful as smoking or alcoholism.”

**ROBERT WALDINGER**

TED talk (2015)  
Robert Waldinger, director of the study, professor of psychiatry at Harvard Medical School.

“Grant and Glueck Study”  
Started 1938. A medical interview, physical examinations, and blood tests were conducted on Harvard University graduates and Boston citizens in the United States

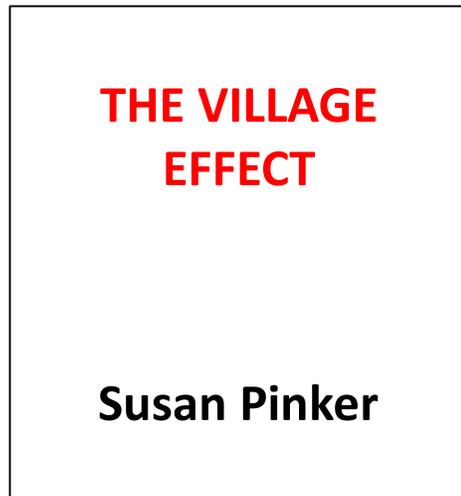
# What is lost in the pandemic



## Face-to-face interaction is associated with longevity

"The Village Effect" explains the effect of face-to-face interaction became a bestseller.

Susan Pinker shows how **face-to-face interaction** is crucial for learning, happiness, resilience and longevity.



**We need the real, in-the-flesh encounters** that tie human families, groups of friends and communities together.

Susan Pinker (1957~)

Developmental psychologist, journalist, author

First edition 2015

**However, the happiness to meet face-to-face has been lost due to the "stay-at-home" lifestyle as a measure to prevent COVID-19.**



# Local government support services with IKIGAI at its core

# Local government support based on "IKIGAI"

## Comprehensive support for infection control and personal health control

### Providing healthcare services based on individual health value

- |                               |                                       |
|-------------------------------|---------------------------------------|
| Frailty measures              | Digital Health Support                |
| Regional healthcare promotion | Medical MaaS                          |
| Epidemiological Study         | Call Center                           |
| Personal Health Check         | Specific health guidance intervention |
| Antigen/PCR Test              | Vaccination                           |
| harmo Service                 | Test Kits Sales                       |

We provides our service to

40

Local governments



We also provide a variety of other services to meet needs.

# Case: Goals of Miyaki Town



## Utilization of Medical Community Center

- to regularly capture and analyze personal health data (body height, weight and BMI etc.)
- health management, sports management and diet management by dietitians (nutrition)

## Health promotion in Miyaki Town



**Utilization of Medical Data** (\*) to analyze the **trends of health status** among Miyaki Town's residents

(\*National Health Insurance data, prescription data held by our company, and prescription data from the pharmacies in Miyaki Town etc.)



To support the smooth planning and execution of **healthcare policies and measures** in Miyaki Town



# PHR in the spotlight

# PHR (Personal Health Record)

## Personal Health Record

A system in which individuals collect their own medical, health, and nursing care information using digital technology and store it centrally. The data can then be provided to medical institutions and used for other purposes.



**Governments, municipalities, and private companies are focusing on the use of PHRs to improve individual health and lifestyle**



# "PHR Service Business Association" to be established, bringing together people from across the private sector



Total 15 private companies from various industries including PHR providers, Insurance, IT, Medical Devices, Telecommunications, Online Medical Care, and Pharmaceuticals participated in June 2022, aiming for establishment in early FY2023.



Study on standardization for effective utilization of data held by various entities related to health and medical care and development of rules to promote quality improvement of PHR services.



CMIC participates as subcommittee secretary on PHR standardization

# Held WASS (Well Aging Society Summit Asia-Japan)



An international event inviting experts from Japan and abroad to address issues emerging from the aging of society and promote solutions through the creation of a new healthcare industry, etc., in cooperation with industry and medical professionals, and global information exchanges.

## INTERNATIONNAL FORUM ON THE SUPER AGING CHALLENGE



中村 和男氏  
シミツホールディングス株式  
会社 代表取締役会長CEO

**Scheduled to speak and participate in a  
panel discussion**

**Tuesday, November 22, 10:50-12:20**

**Significance and Challenges of Promoting the  
Utilization of Personal Health Records (PHR)**



# PHR services deployed by CMIC

# harmo<sup>®</sup> : Healthcare Communication Channel



Health care communication channel for managing "medication information" and future "vaccination information" that individuals should maintain themselves.



**Platform to optimize the medication experience for patients and families**

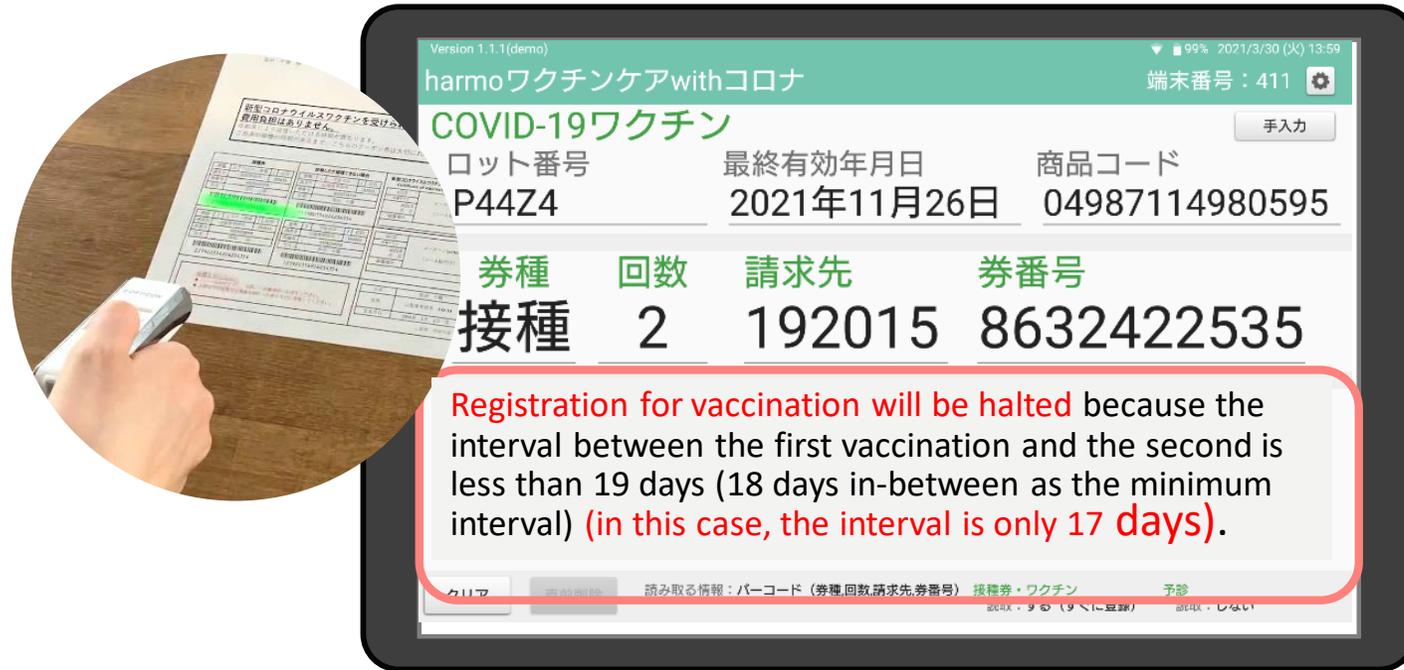


**COVID Vaccination Management**  
**Pediatric Immunization Management**

\*Under PoC (proof of concept)



## Prevent vaccination accidents by reading barcodes at reception



Prevention of vaccination accidents

Number of potential accidents detected

40 Cases

The number of detected cases that are considered to have the potential to become an accident

Number of registrants

Cumulative total

1.05

Million individuals

Delivery record

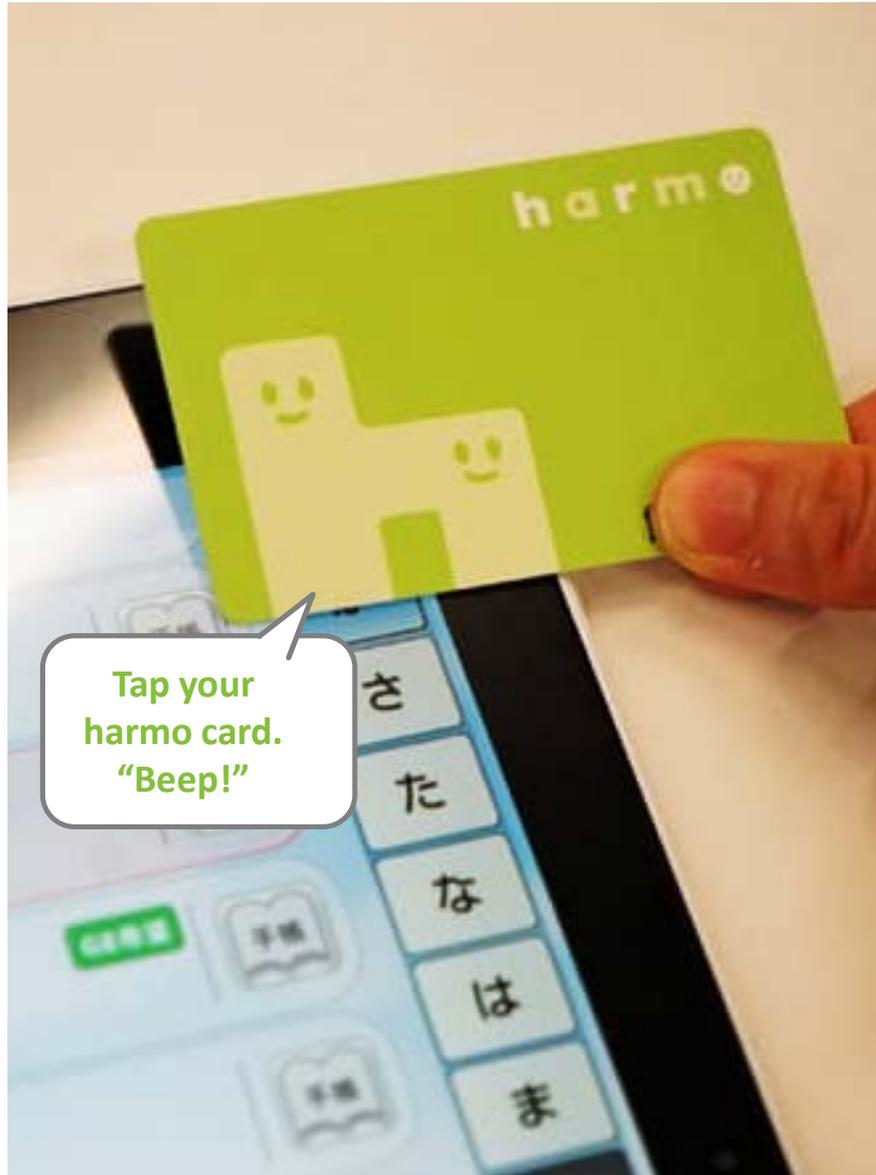
21

Local governments

200

Vaccination sites

As of 2022.8.24



Tap your harmo card. "Beep!"



Take a shot with your smartphone!

## Cherished over 11 years by 400,000 users

System installed

**801** stores

**100** Medical institutions

Number of prescriptions  
Cumulative total  
Over **5** Million pieces

Number of stores using "harmo"  
Over **17,000** stores

Watch all family members  
together  
The circle of harmo!



Accelerates initial reaction at emergency as harmo provides information on regular medications.



An elderly patient decided to have a harmo card when I explained that **“it's useful at emergency”**. Card-type medication record is very convenient.

# “Monitoring”: Initiatives for portable PHR that fit for the elderly



On top of your own health management, PHR enables you to monitor the health status of your loved ones

Kiyomizu-dera Temple, World Heritage



The “Okusuri Omamori (Good Luck Charm)” was created through collaboration across Kiyomizu-dera Temple, CMIC Group, and harmo medication record.

Not for sale



# Towards the realization of personalized healthcare



To let everyone live their once and only life to its fullest, it is important not only to devote our efforts in disease treatment, but also to hold the perspective of IKIGAI: Happiness of each and every person. Such spirit is embodied in CMIC's CREED, which is at the core of our innovation to bring about new healthcare value.





Cautionary statement:

This translation is prepared and provided for readers' convenience only. In the event of any discrepancy between this translated document and the original Japanese document, the original document shall prevail.

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