



Overview of Financial Results for FY2021 2nd Quarter/1H

CMIC HOLDINGS Co., Ltd.
May 14, 2021

Business segments and group companies

- Blue indicates overseas group companies.
- (*) indicates equity method affiliates.



Segment	Products and services	CMIC Group companies (as of end of Mar. 2021)
CRO Business	Services related to pharmaceutical development support and analytical chemistry services	CMIC HOLDINGS Co., Ltd. CMIC Co., Ltd. CMIC ShiftZero K.K. CMIC Korea Co., Ltd. CMIC ASIA-PACIFIC, PTE. LTD. CMIC ASIA PACIFIC (MALAYSIA) SDN. BHD. CMIC Asia-Pacific (Hong Kong) Limited CMIC ASIA-PACIFIC (PHILIPPINES), INC. CMIC ASIA-PACIFIC (AUSTRALIA)PTY LTD CMIC ASIA-PACIFIC (THAI LAND) LIMITED CMIC ASIA-PACIFIC (VIETNAM) LIMITED CMIC (Beijing) Co., Ltd. CMIC DATA SCIENCE VIETNAM COMPANY LIMITED CMIC Pharma Science Co., Ltd. CMIC, INC.
CDMO Business	Services related to drug formulation development and manufacturing support, from formulation design to investigational new drug manufacturing to commercial production of ethical drugs and nonprescription drugs for pharmaceutical companies	CMIC CMO Co., Ltd. CMIC CMO NISHINE Co., Ltd. CMIC CMO Korea Co., Ltd. CMIC CMO USA Corporation CMIC Bio Co., Ltd.
CSO Business	Services provided to pharma companies related to sales & marketing support	CMIC Ashfield Co., Ltd. McCann MDS Inc.*
Healthcare Business	SMO (Site Management Organization) and healthcare services related to treating and maintaining and promoting the health for medical institutions, patients, and general consumers, as well as services related to BPO (Business Process Outsourcing) and human resources	CMIC HOLDINGS Co., Ltd. CMIC HealthCare Institute Co., Ltd. CMIC Solutions Co., Ltd. CMIC Well Co., Ltd.
IPM Business	Provision of new business solutions to pharmaceutical companies, etc. that combine value chains and marketing authorization licenses (intellectual properties) possessed by our Group	CMIC HOLDINGS Co., Ltd. CMIC CMO Co., Ltd. OrphanPacific, Inc.



Main initiatives in the current term

✓ Focus activities in the "Mid-term Plan (FY2019-2021)"

- ◆ In addition to the PVC model, accelerate the IPM solution business that combines marketing authorization licenses
- ◆ Strengthen area competitiveness and promote globalization
- ◆ Create healthcare business

✓ "Healthcare Revolution 2.0" (since July 2020)

- ◆ Transform ourselves from business model centering on pharmaceutical drugs to creation of new healthcare business
- ◆ Create new businesses that will contribute to maintaining and improving personal health
- ◆ Utilize our talents in the healthcare arena

Progress of 2nd quarter of FY2021

✓ Contributing to COVID-19 countermeasures

- ◆ Support for COVID-19 vaccination by local governments
 - Utilization of the COVID-19 vaccination information management system “harmo[®] vaccine care with corona”
 - Call center (to consult about adverse reactions), human resources support
- ◆ Commissioned by local governments, including Setagaya Ward (as social testing), to provide PCR testing services targeting nursing care providers, etc.
- ◆ Support for clinical trials, post-marketing studies, and clinical research
- ◆ Contract manufacturing of drug for the COVID-19 infection

*harmo[®]: Healthcare Communication Channel



Progress of 2nd quarter of FY2021



✓ Creating business that contributes to maintaining personal health

- ◆ A harmo[®] project was designated by the Tokyo Metropolitan government as “Business to Establish the Next Generation Wellness Solution (a Project to Promote Commercialization).”
- ◆ Have joined the Healthcare Open Innovation program hosted by Kouhoukai Group of International University of Health and Welfare, with the aim of developing pre-symptomatic disease prevention services and creating personalized healthcare services utilizing data.
- ◆ Will launch “MONET LABO—HEALTHCARE,” a medical MaaS (Mobility as a Service) specialized business development program, with MONET Technologies.Inc (planned for Jun. 2021)

*MONET: Jointly established by SoftBank Corp., TOYOTA MOTOR CORPORATION, etc.

Progress of 2nd quarter of FY2021



✓ Accelerating & streamlining drug development

- ◆ A demonstration experiment of clinical trial using harmo[®] is ongoing
- ◆ Proposing a new clinical trial model in the age of the New Normal (using digital technology)
- ◆ Launched clinical trial support services targeting digital therapeutics
- ◆ Signed a joint research agreement on blood cancer with the National Cancer Center Japan
 - Promoting projects for the use of data on gene mutations in refractory leukemia, etc.
- ◆ Introduced continuous production equipment, which requires no scale-up from IMP production to commercial production, contributing to the acceleration and cost reduction of development (the operation planned to start in May 2021)

Progress of 2nd quarter of FY2021



✓ Progress of IPM solution

- ◆ OrphanPacific, Inc. received a manufacturing and marketing approval in Japan of *ORLADEYO Capsules 150mg* for the suppression of the onset of attacks in acute hereditary angioedema (HAE) (on Jan. 22, 2021; NHI price listing on Apr. 21)--- a drug that was developed in Japan by BioCryst Pharmaceuticals, Inc. and will be marketed by Torii Pharmaceutical Co.,Ltd. from Apr. 23.
- ◆ Grifols Therapeutics LLC received a foreign exceptional approval of *Lynspad™ for Intravenous Infusion 1000 mg* in Japan (on Jan. 22, 2021; NHI price listing on Apr. 21)---in which OrphanPacific, Inc. has provided support toward the approval as an appointed marketing authorization holder and is expected to support its marketing.

Progress of 2nd quarter of FY2021



✓ **Change of Executive Management (Apr. 2021)**

- ◆ Enhanced the corporate hub function and transferred the Group's back-office operations to a group company to respond to business environment changes in a more agile way
- ◆ Repeal of the executive officer system

✓ **Launched Group-wide "Healthcare Professional Certification System"**

- ◆ Aimed at developing talents who are capable of responding flexibly to the drastically changing healthcare market

Progress of 2nd quarter of FY2021

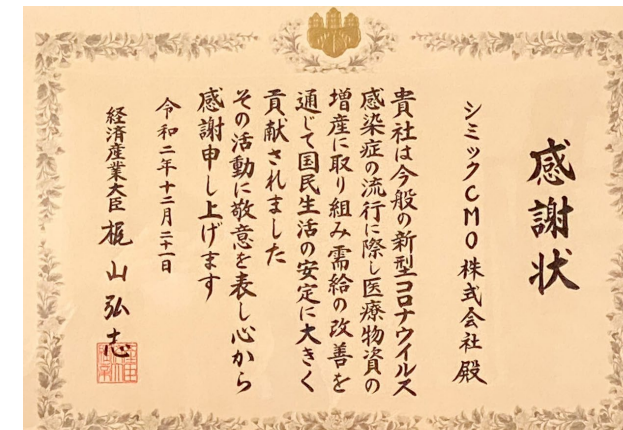
✓ Acquired international standard certification with regard to Information Security Management System (ISMS)

- ◆ Obtained the ISMS-related international standard certification “JIS Q 27001:2014(ISO/IEC27001:2013)” in order for us to continue to strengthen information security and operate appropriately.



認証規格	JIS Q 27001:2014(ISO/IEC 27001:2013)
登録番号	JUSE-IR-470
認証取得事業者	シミックホールディングス株式会社 ICT部 シミック株式会社 データサイエンス事業本部 シミック株式会社 PMS事業本部
登録日	2020年11月27日

✓ CMIC CMO Co., Ltd. received a letter of appreciation from the Ministry of Economy, Trade and Industry as a company that contributed to the increased production of medical supplies in the COVID-19 pandemic.



Consolidated income statement (overview)



	2020/3		2021/3		Change	Percent Change
	Amount	Composition ratio	Amount	Composition ratio		
	(¥ millions)	(%)	(¥ millions)	(%)		
Sales	38,958	100.0	38,645	100.0	(312)	(0.8)
Operating income	1,970	5.1	2,158	5.6	187	+ 9.5
Ordinary income	2,368	6.1	2,368	6.1	(0)	(0.0)
Profit attributable to owners of parent	1,479	3.8	1,222	3.2	(257)	(17.4)
Earnings per share	81.86		67.58			

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



(¥ millions)	2020/3	2021/3	(¥ millions)	2020/3	2021/3
Non-operating income	492	326	Extraordinary income	5	116
Interest income	2	1	Gain on sales of non-current assets	5	–
Foreign exchange gains	–	159	Gain on forgiveness of debts	–	116
Share of profit of entities accounted for using equity method	421	20			
Subsidy income	9	91	Extraordinary losses	114	58
Other	59	53	Loss on retirement of non-current assets	47	25
			Loss on valuation of investment securities	66	32
Non-operating expenses	94	116			
Interest expenses	57	64	Income taxes	674	1,004
Foreign exchange losses	13	–			
Provision of allowance for doubtful accounts	–	27			
Other	23	25	Profit (loss) attributable to non-controlling interests	105	199

Sales & Operating income by segment



		2020/3 Amount (¥ millions)	2021/3 Amount (¥ millions)	Change (¥ millions)	Percent change (%)
CRO Business	Sales	17,898	17,567	(331)	(1.9)
	Operating income	2,930	2,813	(117)	(4.0)
CDMO Business	Sales	10,325	10,505	179	+1.7
	Operating income	147	270	122	+83.5
CSO Business	Sales	4,313	4,190	(122)	(2.8)
	Operating income	437	435	(2)	(0.6)
Healthcare Business	Sales	4,892	5,300	408	+8.3
	Operating income	262	341	78	+29.9
IPM Business	Sales	1,912	1,473	(439)	(23.0)
	Operating income	67	63	(4)	(6.2)
Adjustments	Sales	△384	(392)	(7)	—
	Operating income	△1,875	(1,765)	110	—
Consolidated	Sales	38,958	38,645	(312)	(0.8)
	Operating income	1,970	2,158	187	+9.5

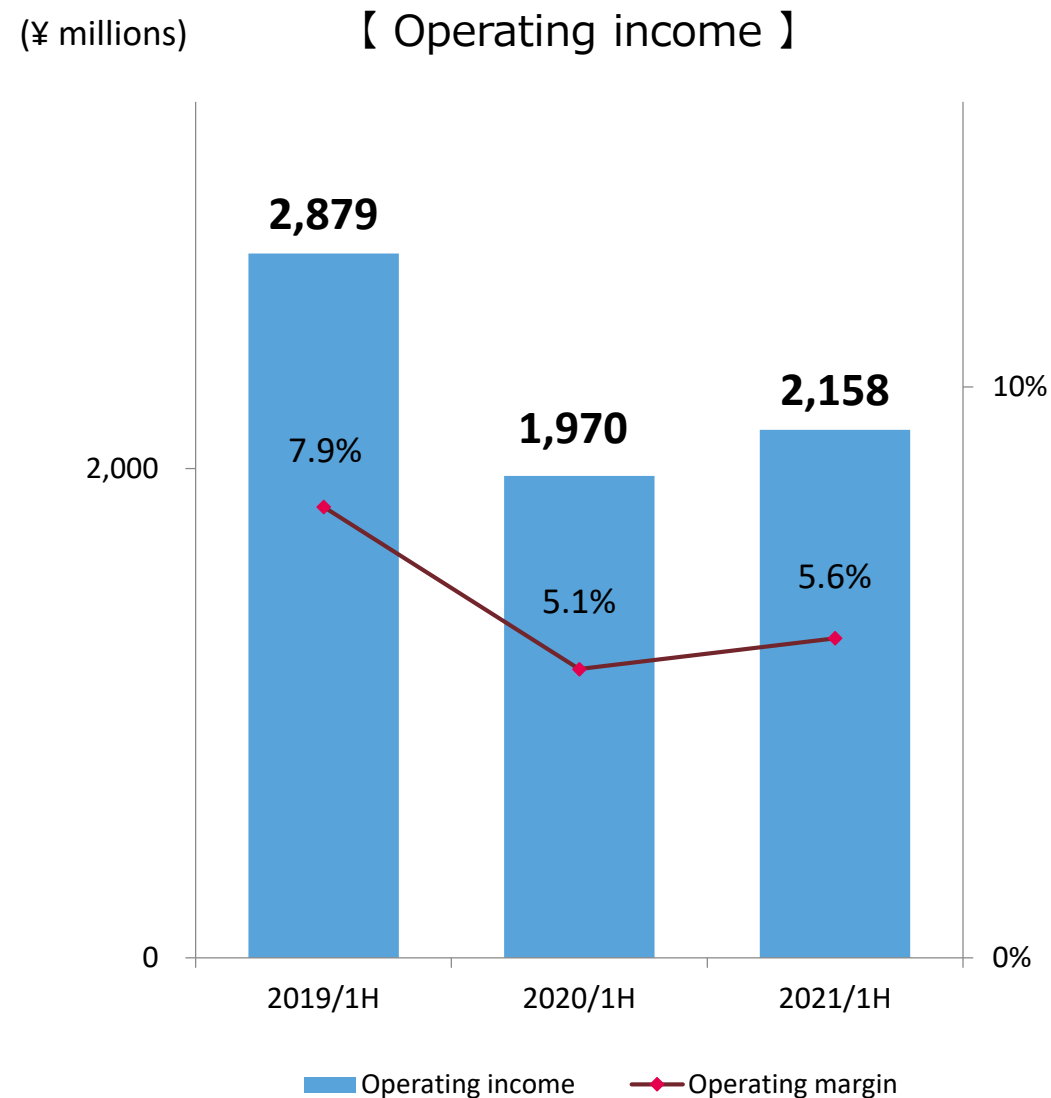
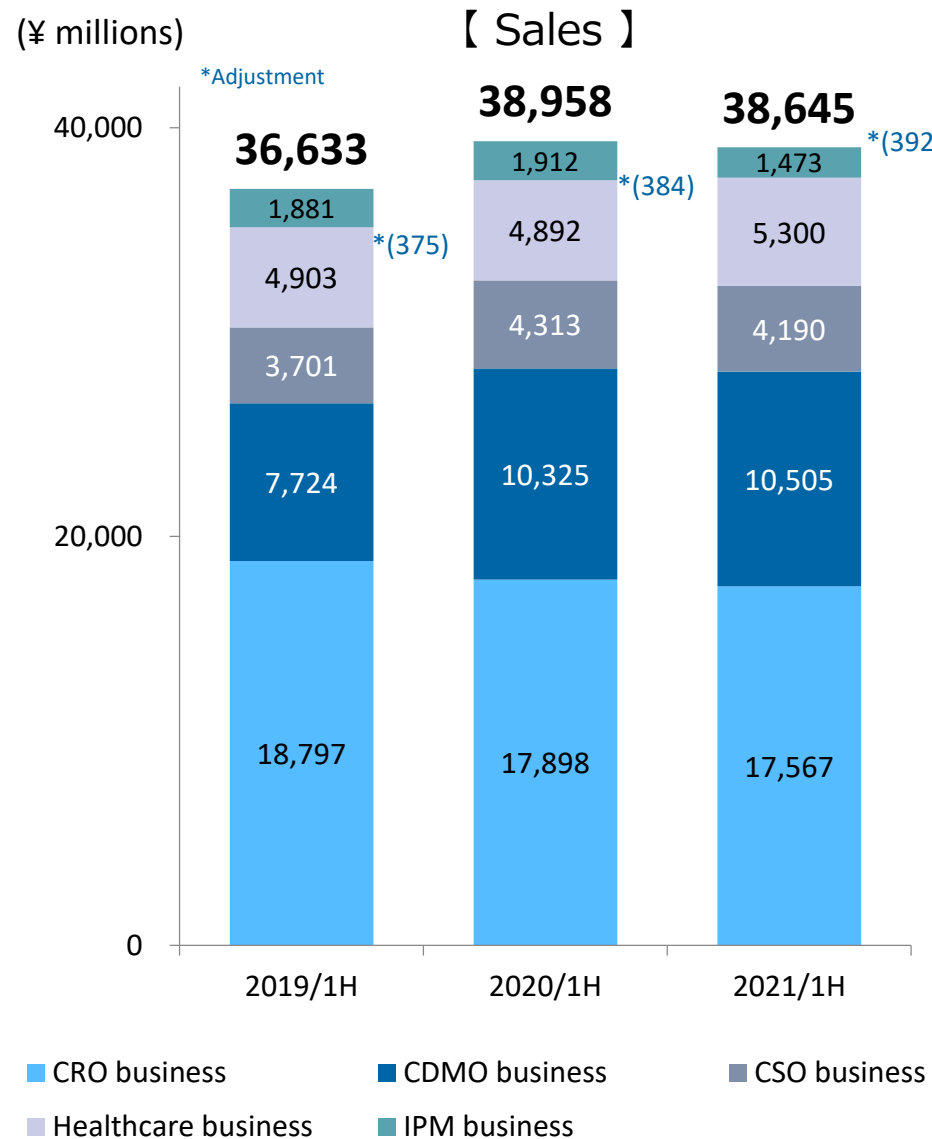
Orders received / Backlog



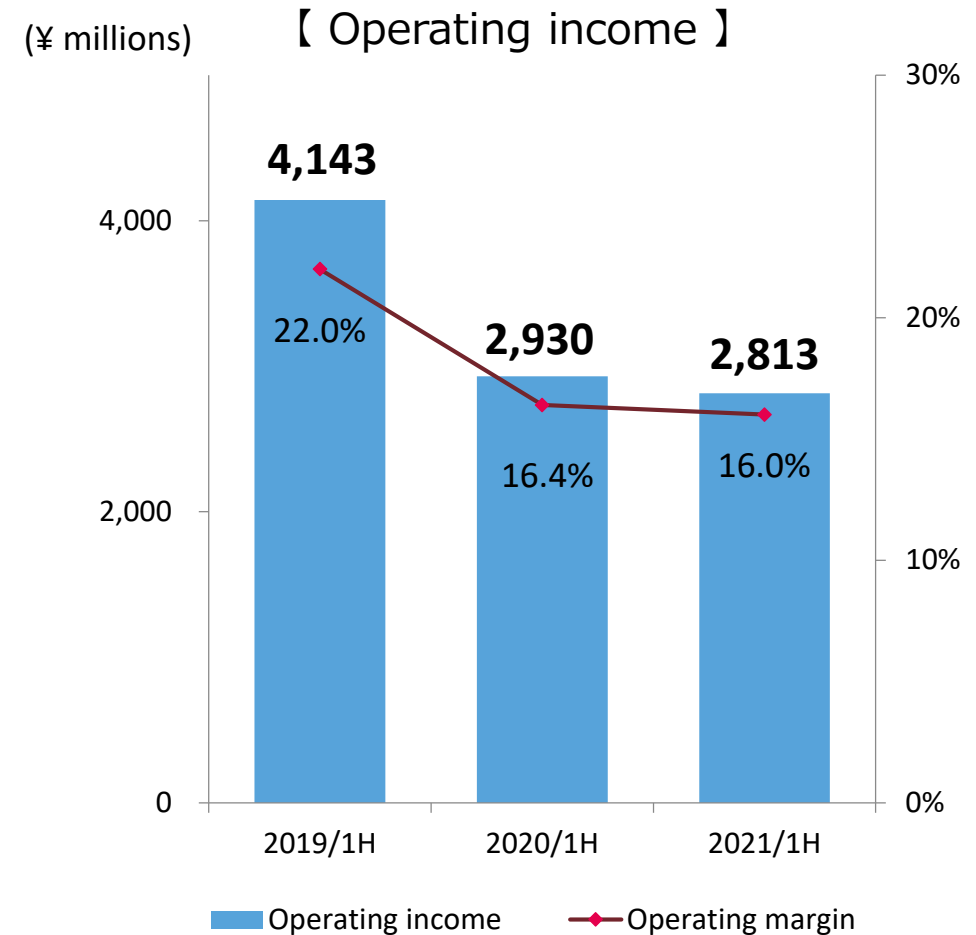
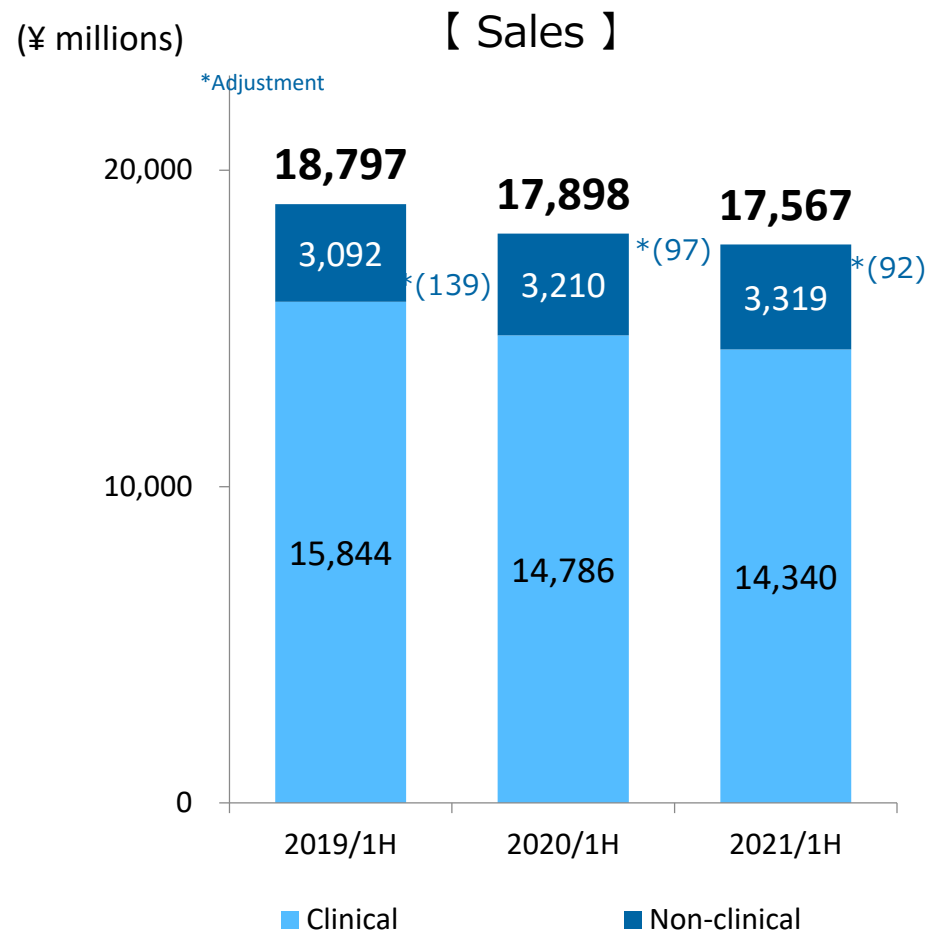
	2020/3		2021/3			
	Orders received	Backlog	Orders received	Percent Change	Backlog	Percent Change
	(¥ millions)	(¥ millions)	(¥ millions)	(%)	(¥ millions)	(%)
CRO Business	18,201	54,041	18,121	(0.4)	57,303	+ 6.0
CDMO Business	9,248	4,263	10,114	+ 9.4	5,062	+ 18.7
CSO Business	4,077	3,786	4,920	+ 20.7	3,862	+ 2.0
Healthcare Business	5,313	11,864	7,249	+ 36.4	14,026	+ 18.2
Total	36,840	73,956	40,405	+ 9.7	80,254	+ 8.5

- The orders received increased in segments, including the Healthcare and CSO businesses, which contributed to 9.7% growth compared with the same period of the previous year.
- The backlogs increased in all the businesses segments.
- Accounts only for the firm business orders in the CDMO business backlog. The annually scheduled orders presented by customers are not equivalent to firm orders so are not included in the backlog.
- The order status excludes the IPM business, for its business conditions are different from those of contract business.

Trends in consolidated sales & operating income



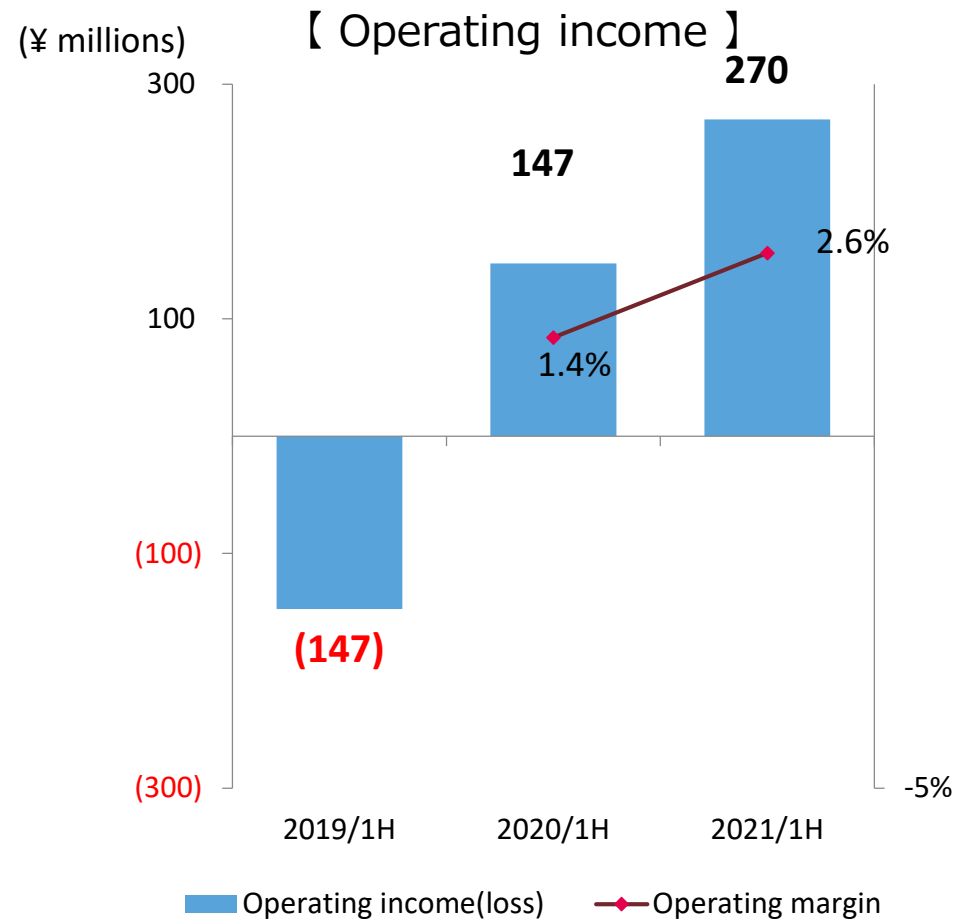
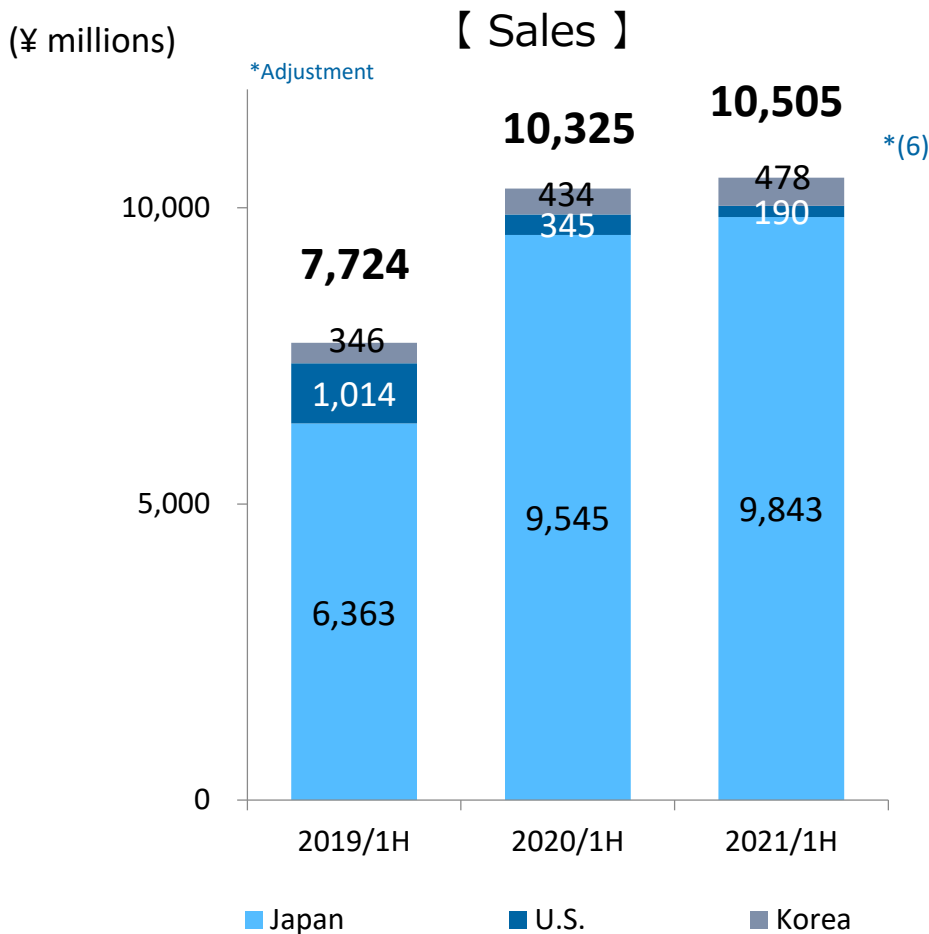
Contract Research Organization (CRO) Business



- Support overseas companies entering the Japanese market and non-healthcare companies entering the healthcare sphere, and promoted measures to address increasingly sophisticated development needs (biopharmaceuticals, etc.), while helping to maximize the speed of drug development by offering one-stop service from non-clinical to post-marketing. Propose the improvement of efficiency of clinical trial process by using harmo®, as well as a new clinical trial model.

- Sales were below the same period of the previous year due to factors such as the weakness in orders for clinical operations in the previous consolidated fiscal year as a result of the spread of COVID-19 infection. Operating income was below the same period of the previous year due to factors such as a decrease in revenue from clinical operations, despite an increase in non-clinical operations.

Contract Development Manufacturing Organization (CDMO) Business



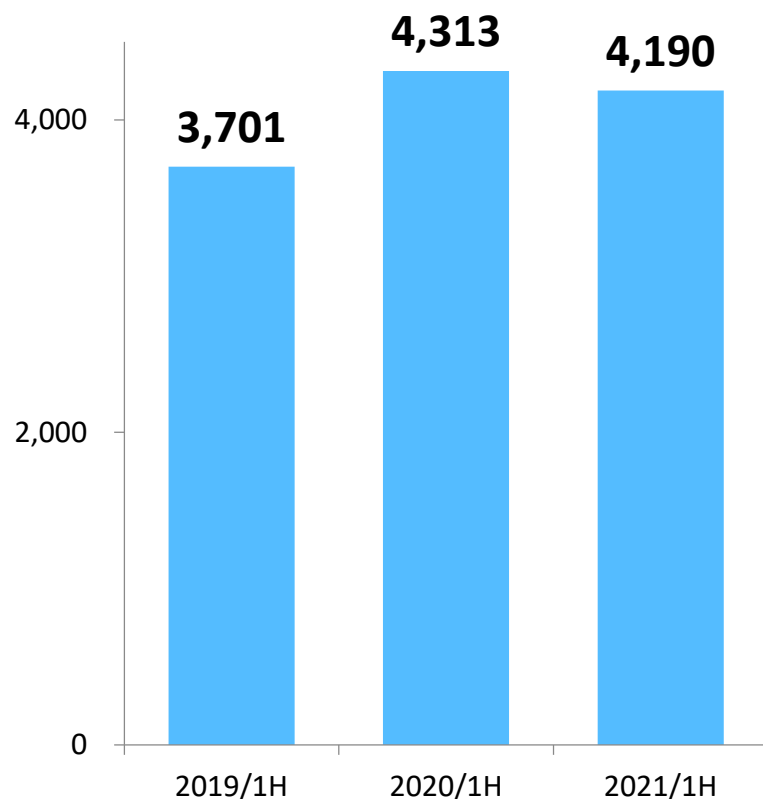
- Improve technical capabilities and quality, develop a low-cost production structure, and enhance competitiveness through strategic capital investment as a global pharmaceutical drug manufacturing platform that includes formulation design, investigational new drug manufacturing, and commercial production
- Focus on a large-scale commercial production project that is scheduled to start production in the fiscal year ending September 30, 2022, the launch of new facility and production line in the United States, and the acquisition of new projects.
- Sales were above the same period of the previous year due to factors such as an increase in contracted production volume. Operating income was above the same period of the previous year due to the increase in sales, despite prior investment costs for the contract manufacturing business of biopharmaceutical APIs.

Contract Sales Organization (CSO) Business



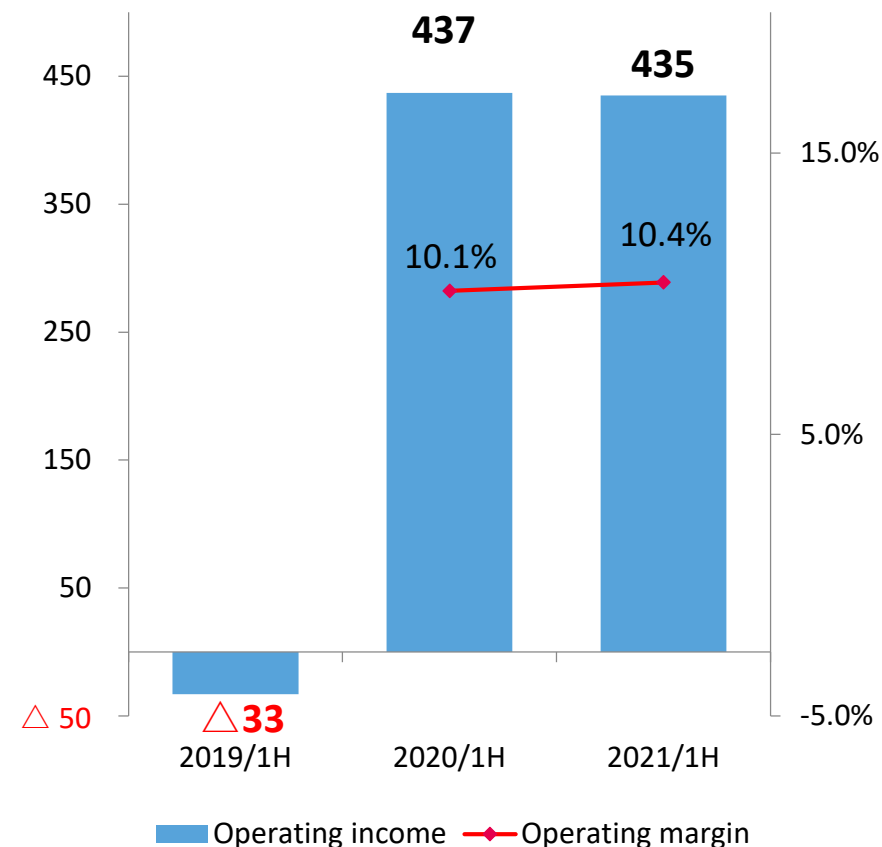
(¥ millions)

【 Sales 】



(¥ millions)

【 Operating income 】

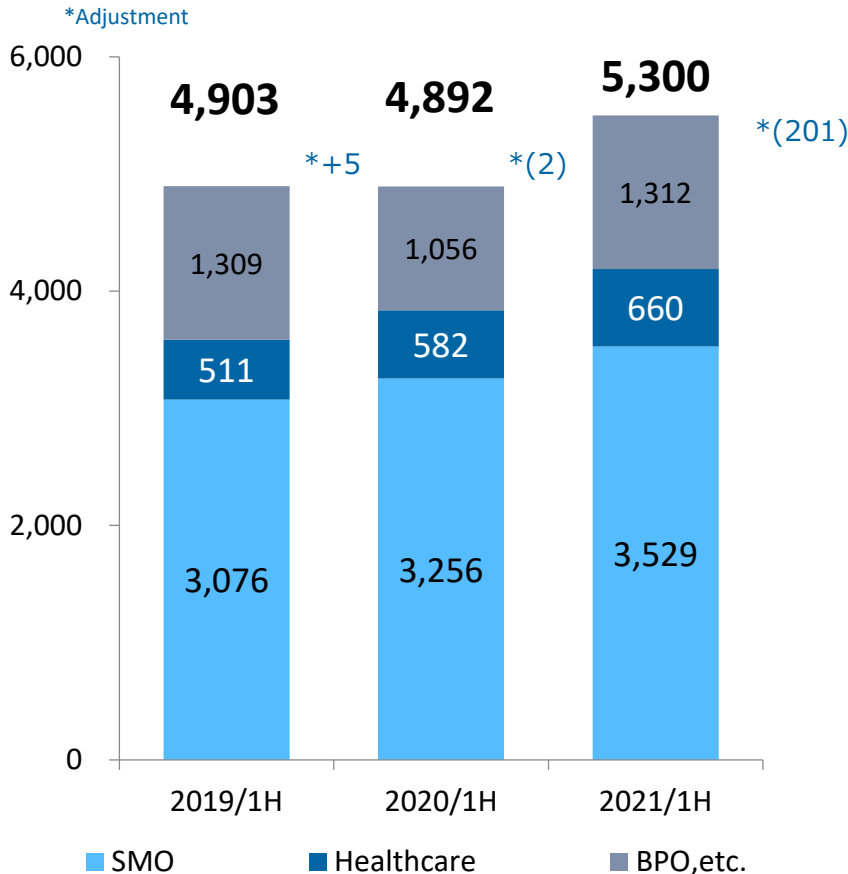


- In addition to the medical representative (MR) dispatch and other related new services, strengthen the sales activities for Medical Affairs-related operations and provide comprehensive solution that combines multiple communication channels and various services.
- Sales and operating income were at the same level as the same period of the previous year, despite a slight decline in the operation rate in the MR dispatch services.

Healthcare Business

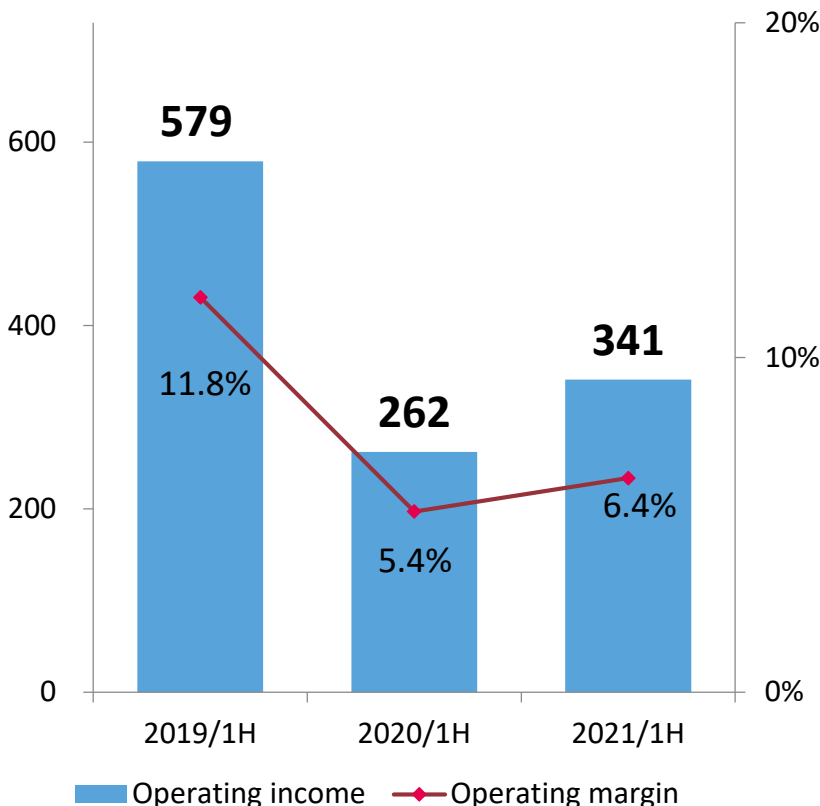
(¥ millions)

【 Sales 】



(¥ millions)

【 Operating income 】

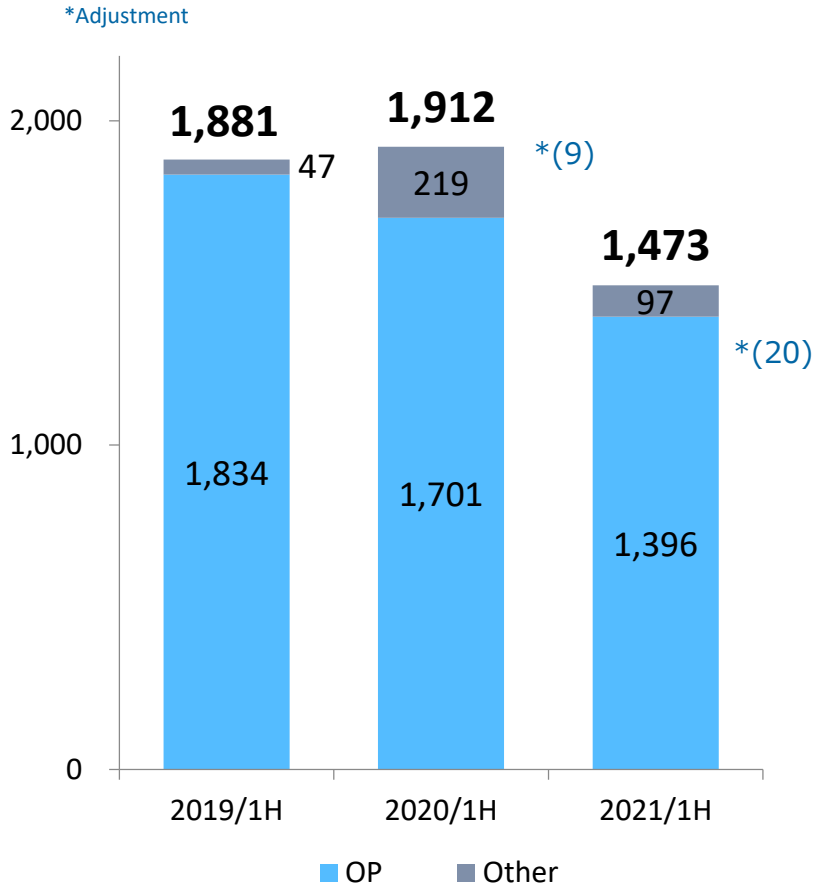


- Focus on supporting the development of effective treatment and preventive measures against COVID-19 infection, as well as supporting the setup of PCR testing and vaccination systems by local governments.
- Work on the healthcare communication channel harmo® business and create business that contributes to the early detection of disease and prevention of disease aggravation.
- Sales were above the same period of the previous year due to growth in the SMO operations, etc. Operating income was also above the same period of the previous year due to an increase in sales, despite prior investments for the creation of new healthcare business.

Innovative Pharma Model (IPM) Business

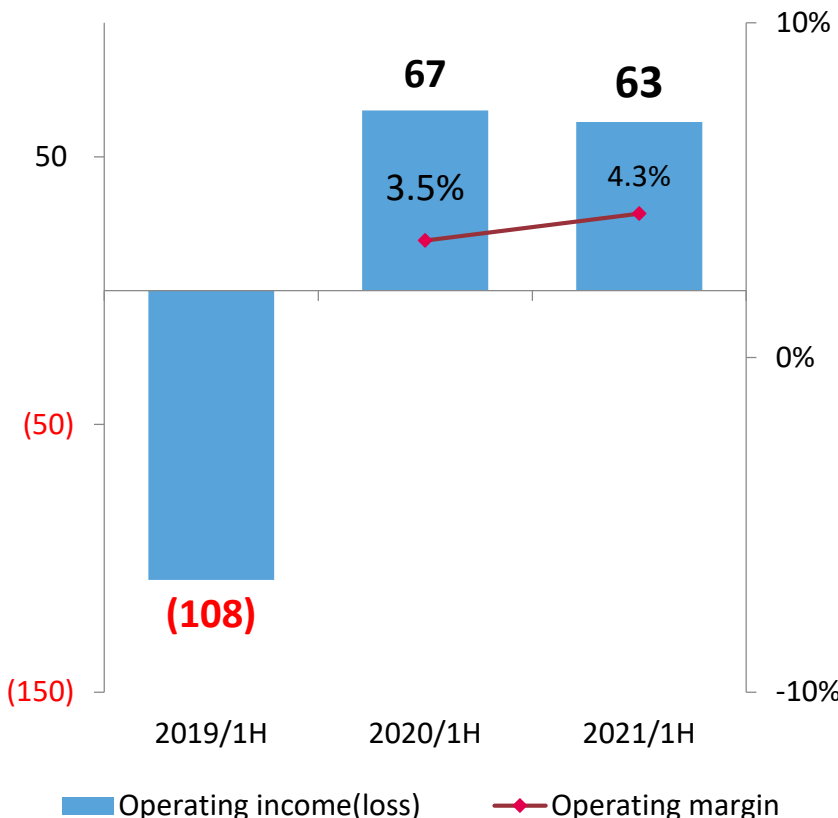
(¥ millions)

【 Sales 】



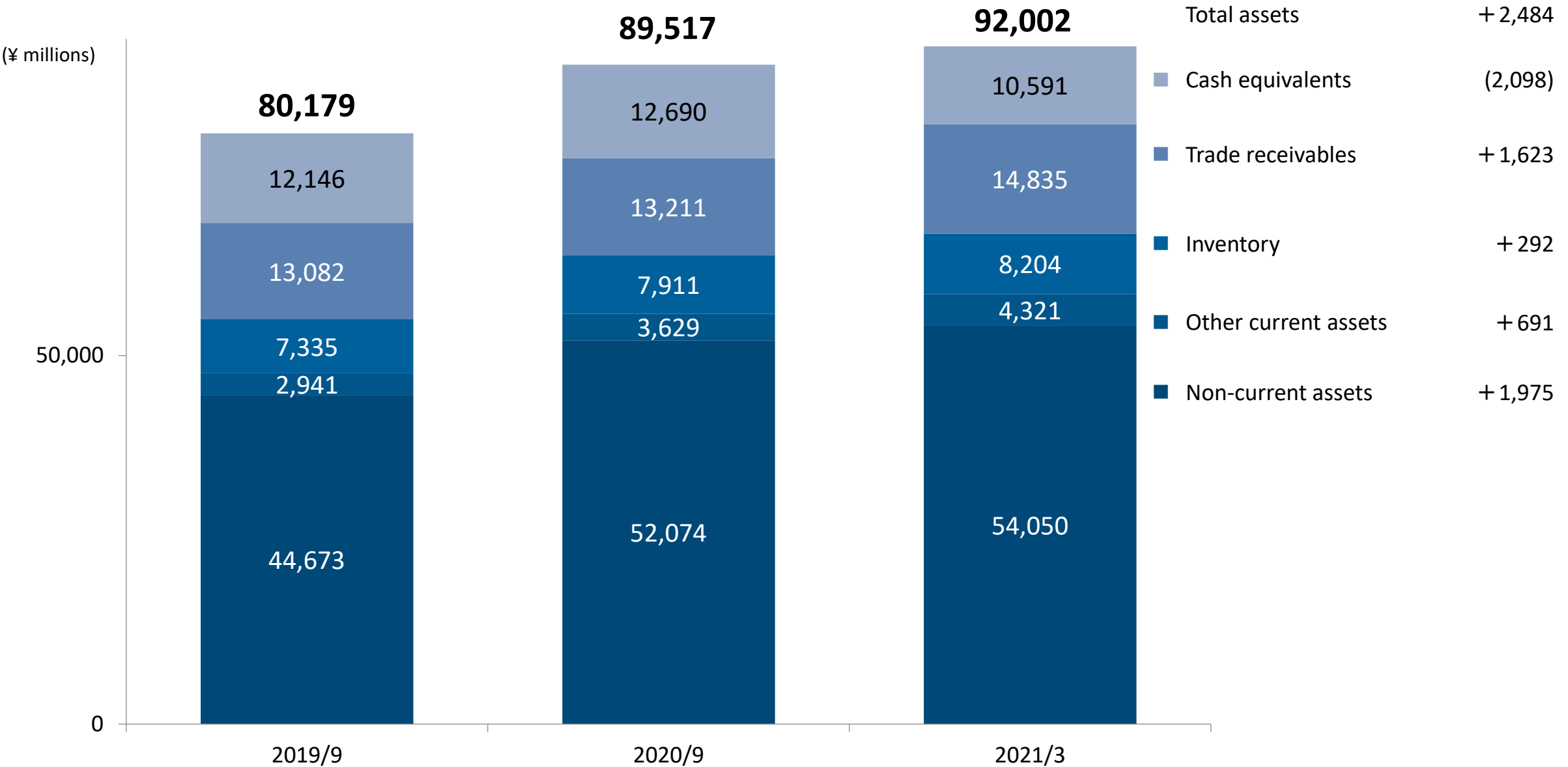
(¥ millions)

【 Operating income 】

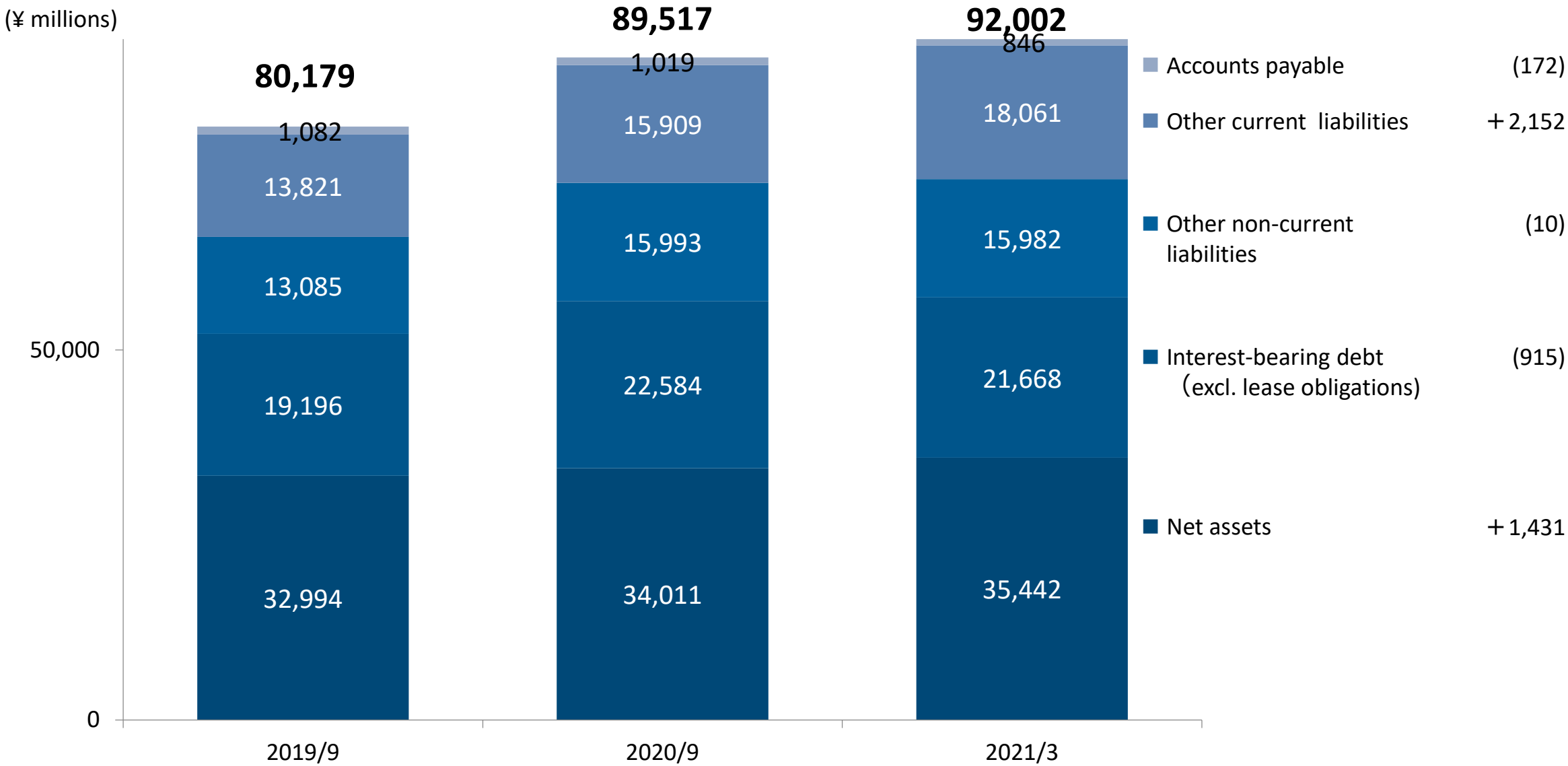


- In addition to selling orphan drugs, etc., including products developed in-house, provide the IPM platform that includes supporting foreign pharmaceutical companies entering the Japanese market and providing strategic options to pharmaceutical companies following changes in their business models. Multiple projects are progressing with increased demand from foreign pharmaceutical companies to use our IPM platform. In January 2021, two products involved by our IPM business received a manufacturing and marketing approval in Japan.
- Sales were below the same period of the previous year due to a decrease in sales volumes of some products. On the other hand, operating income was at the same level as the same period of the previous year due to effects such as the one from reduction in cost.

Consolidated balance sheet (assets)



Consolidated balance sheet (liabilities and net assets)



Cash Flows



(¥ millions)	2020/3	2021/3	Increase (decrease)
Cash flows from operating activities	1,574	2,089	+515
Cash flows from investing activities	(2,519)	(2,730)	(210)
Cash flows from financing activities	3,156	(1,412)	(4,568)
Effect of exchange rate change on cash and cash equivalents	(8)	(47)	(39)
Net increase(decrease) in cash and cash equivalents	2,202	(2,100)	(4,303)
Increase in cash and cash equivalents resulting from inclusion of subsidiaries in consolidation	—	1	+1
Decrease in cash and cash equivalents resulting from exclusion of subsidiaries from consolidation	(14)	—	+14
Cash and cash equivalents at beginning of period	12,144	12,688	+543
Cash and cash equivalents at end of period	14,332	10,589	(3,743)

【Key factors】

(Cash flow from operating activities)

- Increase in cash flow due to profit before income taxes and depreciation
- Decrease in cash flow due to payment of total income tax and increase in notes and accounts receivable -trade

(Cash flow from investing activities)

- Expenditure from the acquisition of tangible non-current assets in the CDMO business

(Cash flow from financing activities)

- Proceeds from long-term loans payable
- Expenditure from repayments of short-term loans and commercial papers, etc.


The impacts of the priority measures to prevent the spread of disease and the state of emergency associated with the spread of COVID-19 infection

- Potential impacts may include delays in collecting data, etc. due to restrictions on visits to medical institutions and a decrease in contracted production volume due to decreased sales volumes of pharmaceuticals.
- With the above, we will strive to enhance order-taking activities for clinical trials and post-marketing surveillance projects related to the COVID-19 infection and expand support services for vaccination activities by local governments.

At this point in time, there are no changes to the “consolidated earnings forecast for the fiscal year ending September 30, 2021” announced on November 6, 2020.



Developments on Our Business



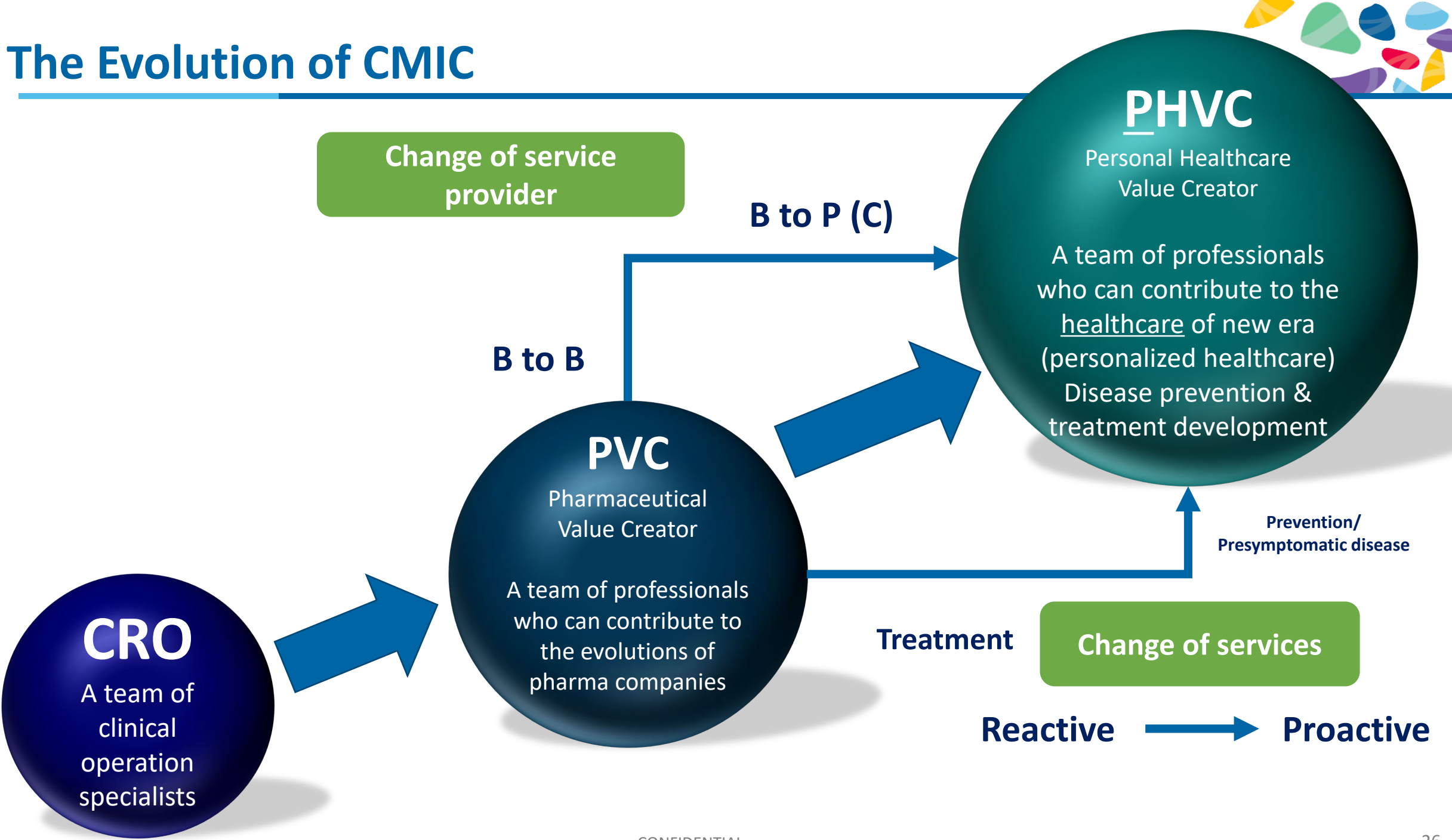
Kazuo Nakamura, Ph.D.
Representative Director, Chairman and CEO



Healthcare Revolution 2.0

July 2020 - June 2022

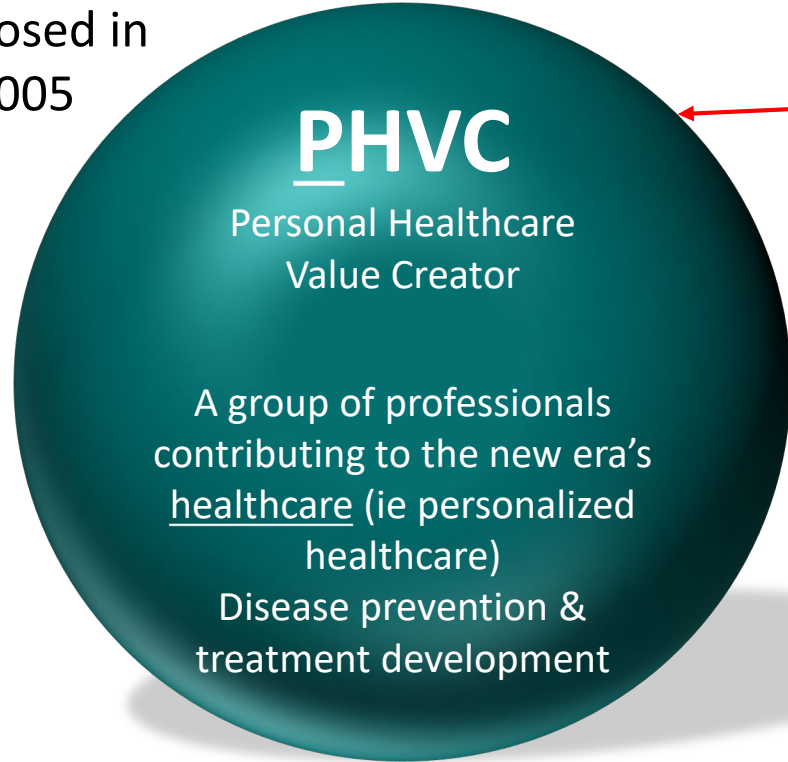
The Evolution of CMIC



Healthcare Revolution – The Process to Actualize PHVC



Proposed in
2005



Personal Health Value

Established in
2015



Our Creed

CMIC Group will bring innovation to healthcare so that all people, regardless of age, gender or race, can live their one and only lives according to their own will.

Whether in youth, when potential has yet the blossom, or in later years, when the fruits of one's life are maturing, every individual has an equally earnest desire to live every moment to its fullest. We wish to genuinely answer each and every one of these wills to live.

To achieve this, we aspire to always challenge ourselves for a better future. By evolving and gaining new perspectives, we will create value out of our unwavering determination, and continue to contribute to society and humanity.

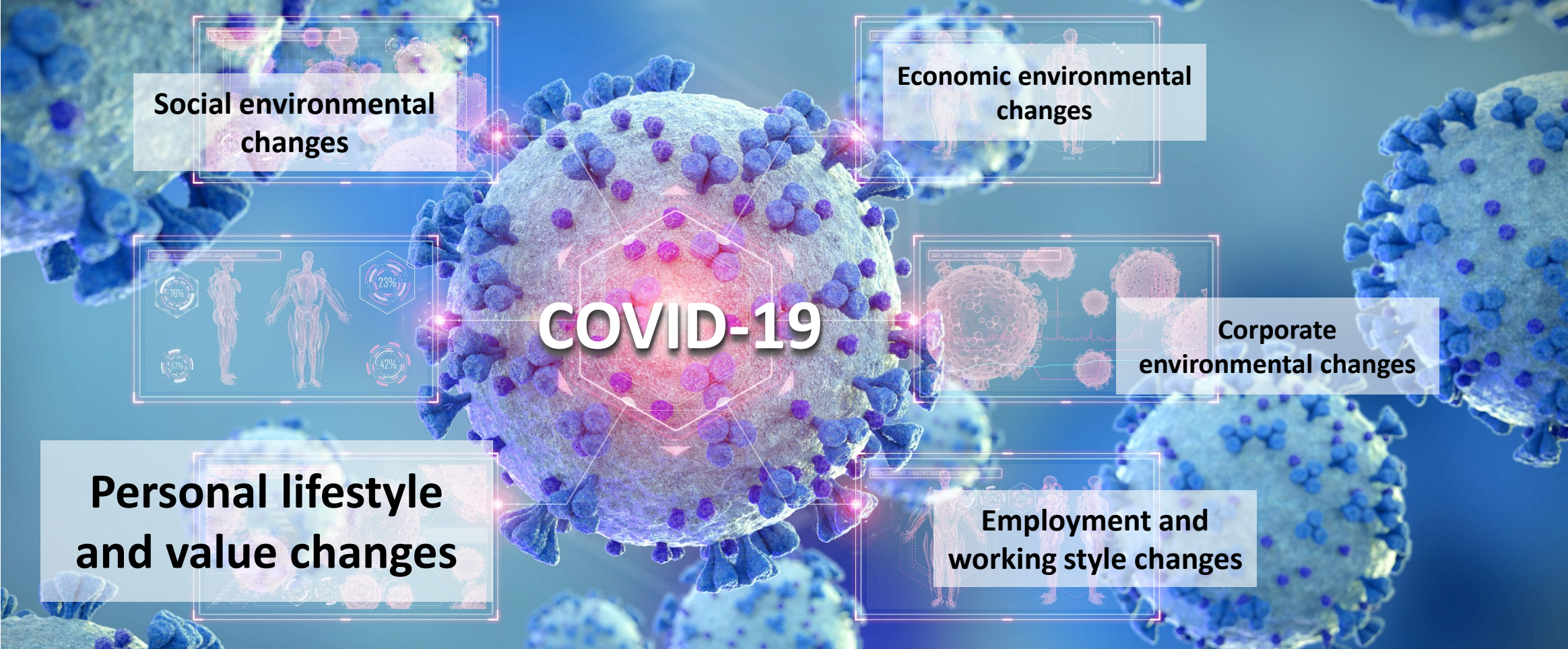
PHVC = To provide healthcare services based on individual health values

**Not an existing concept
such as conventional medicine-based
treatment/prevention/presymptomatic disease**



COVID-19 Pandemic Prevalent Worldwide

Drastic Environmental Changes Due to Pandemic



Drastic Changes around Healthcare



- ◆ Aggravating healthcare financing
- ◆ Shifting to personalized medicine
- ◆ Annual drug price revision
- ◆ Generics quality issues
- ◆ Advancing digitalization
- ◆ Comprehensive disease care, etc.

The world largest scale of
vaccination



Countries battling to
secure vaccines



New drug
development



Digitization
accelerated



With conventional common sense overturned,
going from living in harmony to living in hybridity, toward a new business model

CMIC Group's COVID-19 Related Support Activities



Information communication

Contributing to eliminating users' uncertainties and preventing infection spread

Gathering & releasing COVID-19 related information officially announced by governmental institutions such as Prime Minister's Office and Ministry of Health, Labour and Welfare via the harmo® smartphone app

Testing

■ PCR testing

Supporting PCR testing (social testing) operations targeting nursing care offices, etc.

Development support

Providing services for all operations related to drug development

- **CRO**
Supporting the smooth implementation of clinical trials/PMS
- **CDMO**
Contracted with IMP manufacturing
- **SMO**
Supporting clinical trial operations for medical institutions

Vaccination support

■ Partnerships with local governments

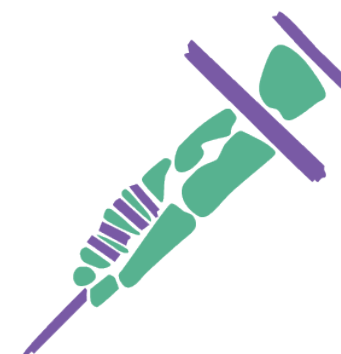
Partnerships concluded with multiple local governments (Yamanashi Prefecture, 7 municipalities in the Mt. Yotei foothills in Hokkaido, etc.)

■ Vaccination: Supporting smooth vaccination rollout

- Call centers
- Supporting local government system setups
- Creating a flow manual
- Supporting vaccination site setups

■ Vaccination information management

Entering/aggregating vaccination information and enabling long-term post-vaccination follow-ups on the COVID-19 vaccination information management system "harmo® Vaccine Care with Corona"





Characteristics of Vaccination Support Business for Local Governments



✓ Providing total support for local governments utilizing clinical trial support experiences

- Providing support for the overall vaccination operations such as creating a manual, providing call center services, introducing HCPs, dispatching healthcare human resources, and utilizing PHR (harmo[®] vaccine care with corona)

✓ Established stable system operations

- Already in operation in an infant vaccination demonstration experiment in Kawasaki City
 - Avoiding errors in vaccination interval, vaccine mix-up, etc.
 - Registering/gathering vaccination information very quickly using barcodes
 - Monitoring progress real-time



harmoワクチンケアwithコロナ

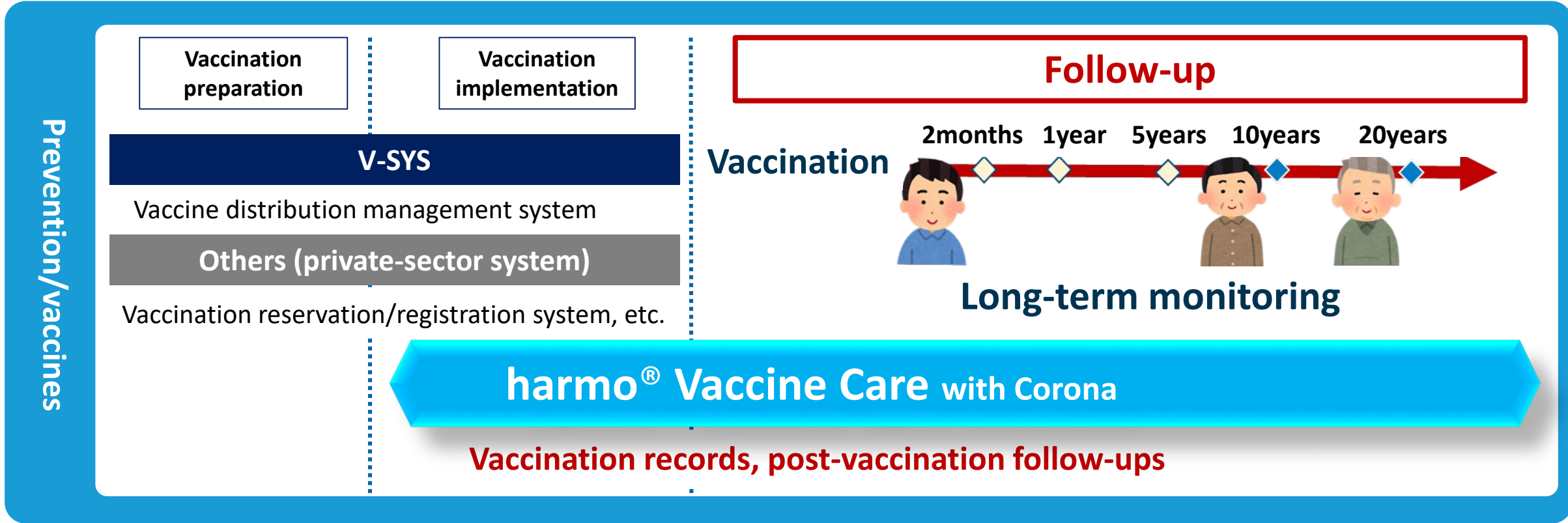


Tablet



Barcode reader

COVID-19 Vaccine/Infection Related System (Overview)



harmo[®] Vaccine Care with Corona: An Outlook

There is the possibility that an adverse reaction may occur some time after the COVID-19 vaccination. For this, we are planning to release a smartphone app this summer that enables follow-ups based on the exact lot numbers.

Moderna says possible allergic reactions to COVID-19 vaccine under investigation

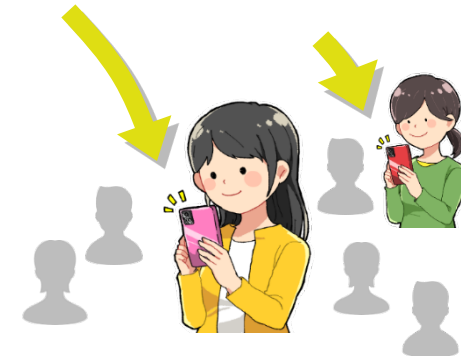
Moderna Inc said on Tuesday it had received a report from California's health department that several people at a center in San Diego were treated for possible allergic reactions to its COVID-19 vaccine from a particular batch.

The company's comments come after California's top epidemiologist on Sunday issued a statement recommending providers pause vaccination from lot no. "41L20A" due to possible allergic reactions that are under investigation.

(Source)

<https://www.reuters.com/article/us-health-coronavirus-moderna-idUSKBN29O2C5>

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Local Government Support Business Cases

Local Government Support Business Cases

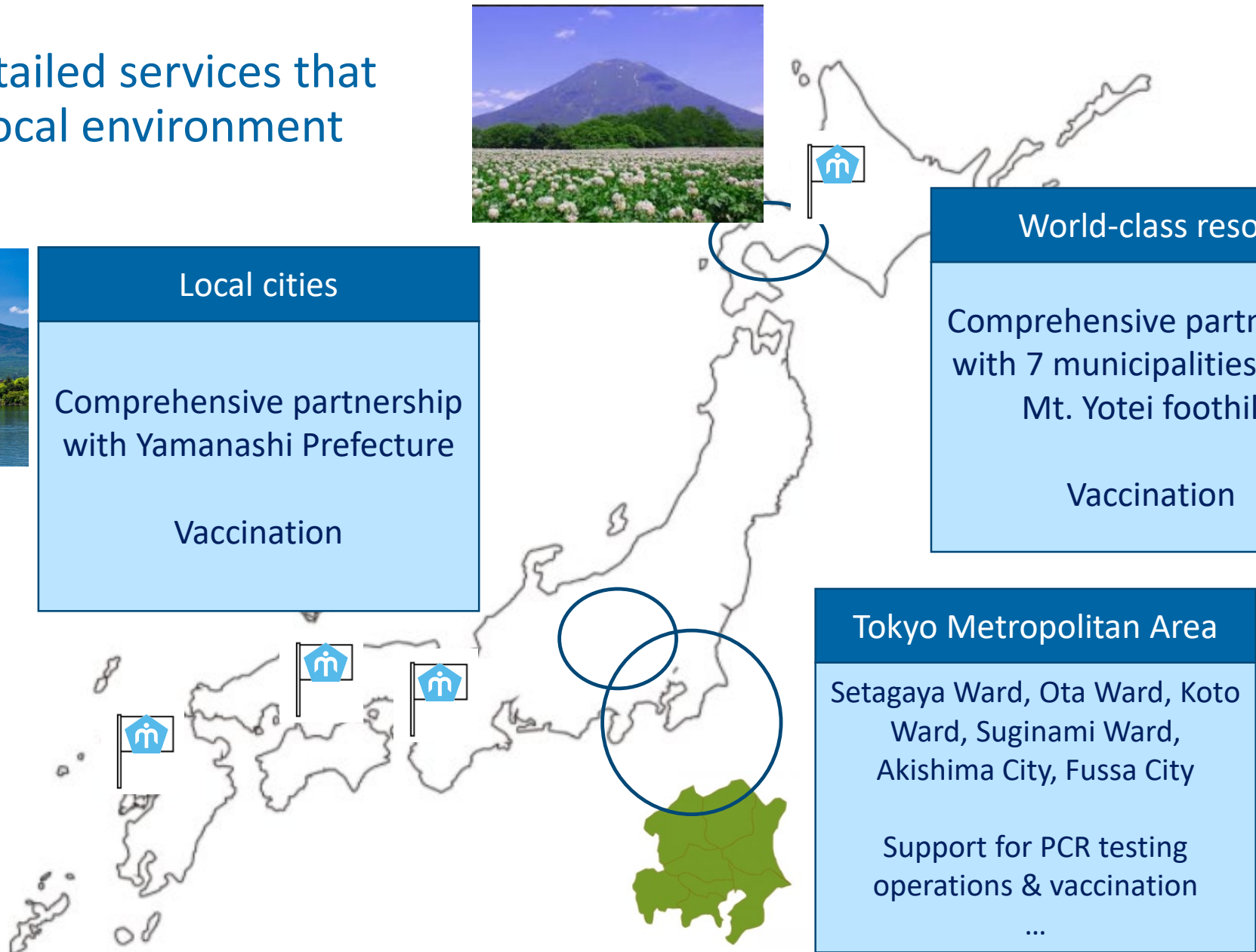
Requires detailed services that reflect the local environment



Local cities
Comprehensive partnership with Yamanashi Prefecture
Vaccination

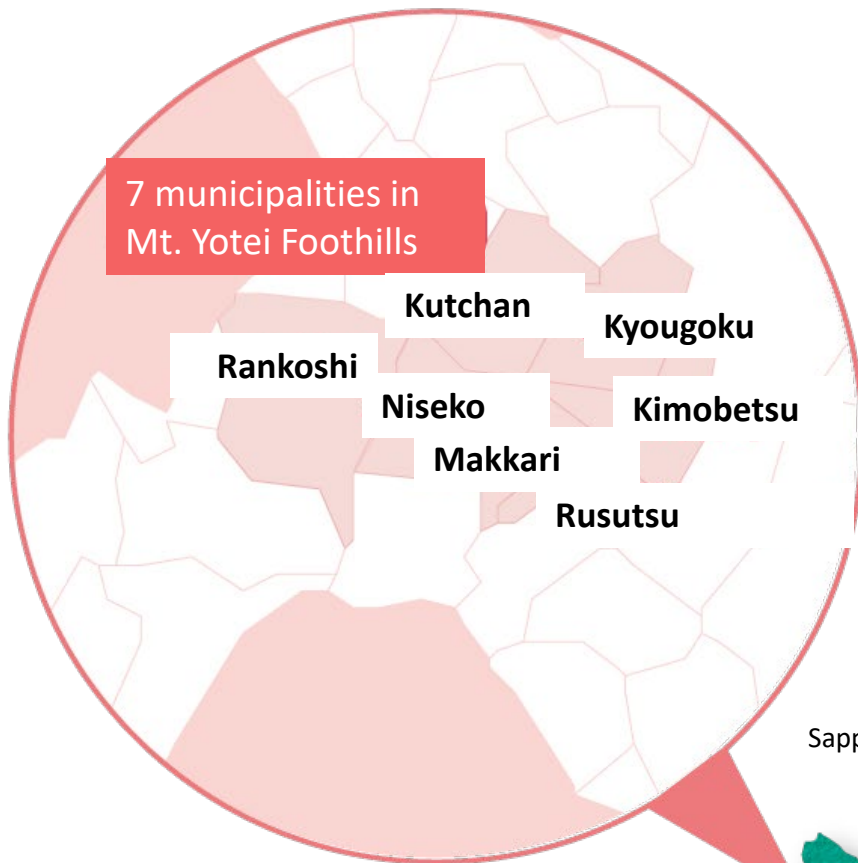


World-class resort
Comprehensive partnership with 7 municipalities in the Mt. Yotei foothills
Vaccination



Tokyo Metropolitan Area
Setagaya Ward, Ota Ward, Koto Ward, Suginami Ward, Akishima City, Fussa City
Support for PCR testing operations & vaccination
...

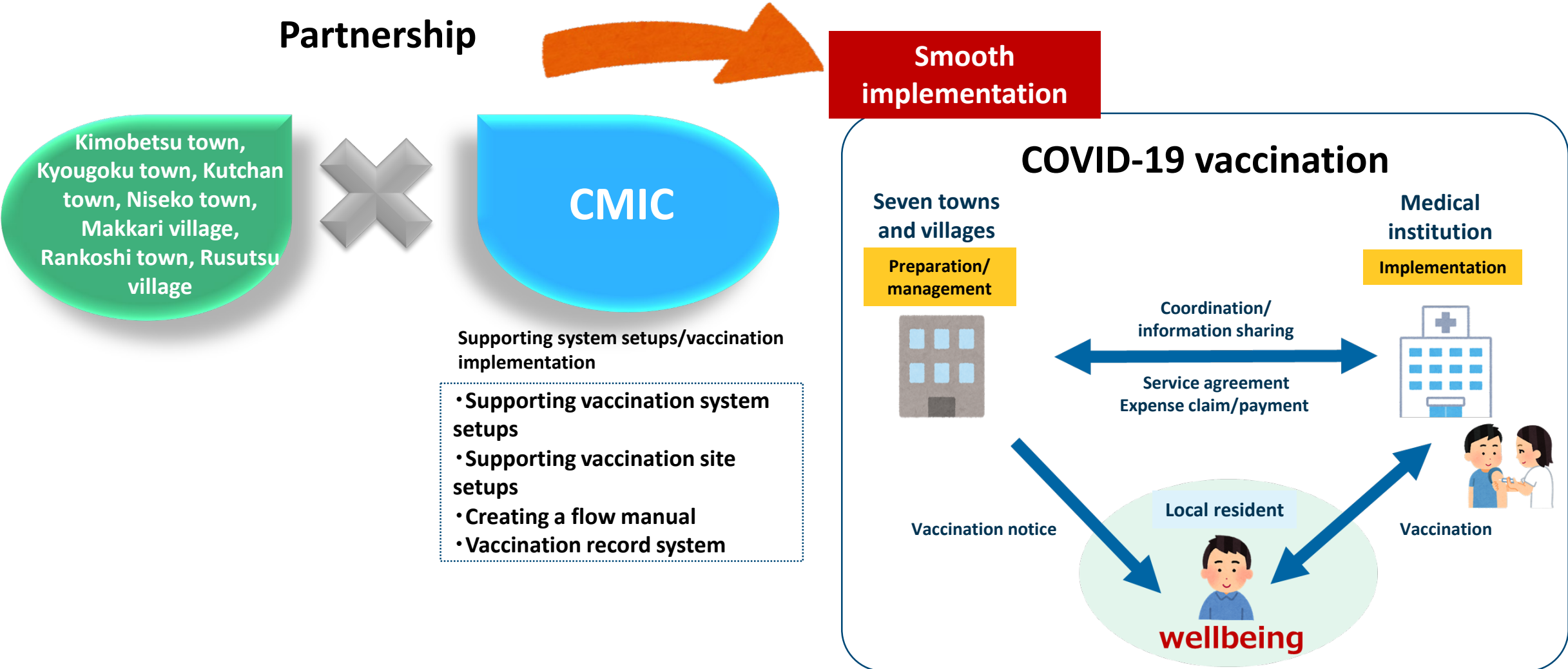
7 Municipalities in Mt. Yotei Foothills / World-Class Resort “Niseko”



About the area in the Mt. Yotei foothills

Consists of seven towns and villages (five towns and two villages) surrounding Mt. Yotei, located in the southwestern part of Hokkaido. The total population is 34,310, and the area is known for high-quality agricultural produce produced in rich natural environment and a worldly famous ski resort with quality powder snow. One of the representative resort areas in Japan.

Partnership between 7 Municipalities within Jurisdiction of Shiribeshi General Subprefectural Bureau and CMIC Group





Post-Vaccination

Acceleration of Healthcare Revolution 2.0 Triggered by Pandemic



- The global battle against the pandemic continuing even after vaccination started

Variants emerging, vaccination rate, vaccine efficacy

- The needs to address local governments' challenges

- Individual health/disease awareness raised

- The expanding scope of activities by healthcare professionals

Healthcare Revolution 2.0



1



Transformation from Pharma Model to Innovative Healthcare Pharma Model

harmo® (Healthcare Communication Channel)

- Innovating the value chains & supply chains of pharma
- (To maximize the speed of access to market)

2



Healthcare system revolution (Realization of CMIC CREED)

Launched **CMIC Healthcare Station**

- To provide services for health management/“ME-BYO” (presymptomatic disease), prevention, disease management, etc. with the use of data

3



Creating talent value in healthcare business

- Developing **healthcare professional talents**



Cautionary statement:

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