DIGITAL TRANSFORMATION OF ASTELLAS PHARMA

Media Briefing - January 21, 2022

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

Information about pharmaceutical products (including products currently in development) which is included in this material is not intended to constitute an advertisement or medical advice.

Agenda

1 **Reasons to Engage in Digital Transformation**
Naoki Okamura
Chief Strategy Officer and Chief Financial Officer, Chief Business Officer

2 **Digital Transformation of Astellas Pharma**
Shinya Suda
Senior Vice President, Information Systems

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Reasons to Engage in Digital Transformation

Naoki Okamura

Chief Strategy Officer and Chief Financial Officer, Chief Business Officer
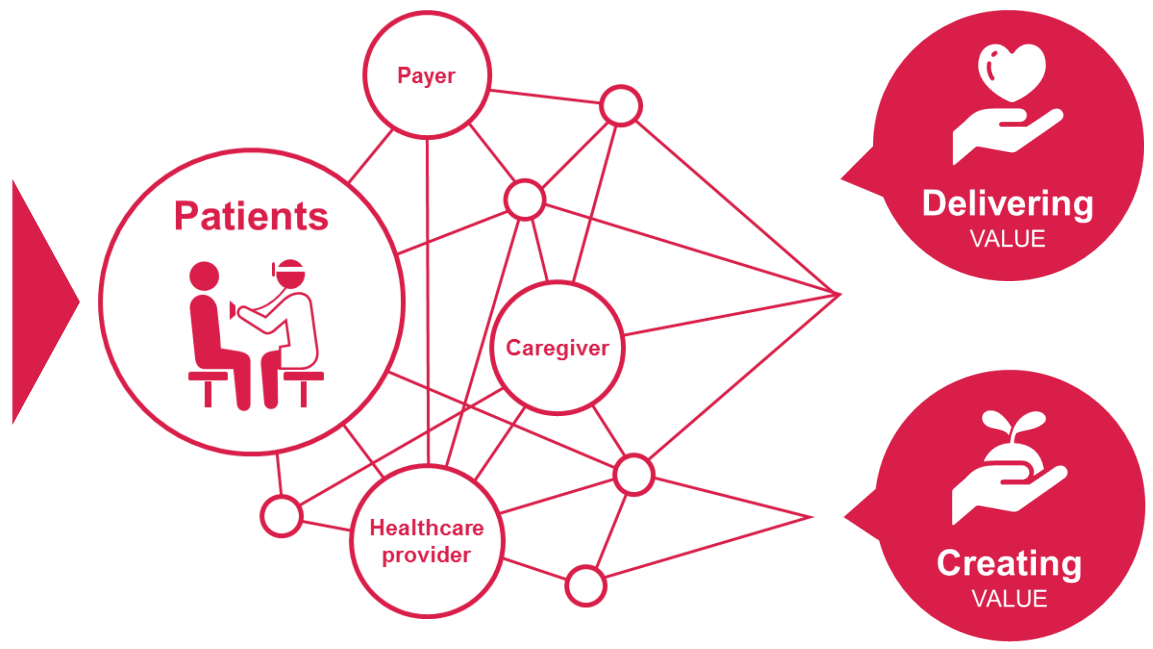
Vision

On the Forefront of Healthcare Change to Turn Innovative Science into **VALUE for Patients**

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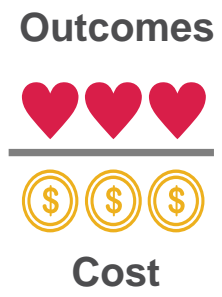
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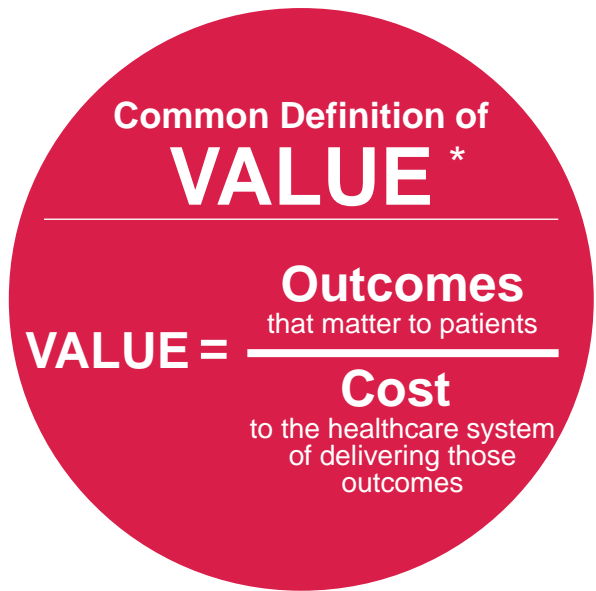**Common Definition of VALUE** *

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

Outcomes

Cost

Double the outcomes

Double the VALUE

One third the cost

Triple the VALUE

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

Corporate Strategic Plan 2021	The next chapter in Astellas' transformation to be a **cutting-edge, VALUE-driven life science innovator**
Strategic Goals	Our evolving strategic path and priorities, detailed to bridge effectively to execution.
Organizational Health Goals	The internal environment that will unlock our full potential to innovate and execute.
Performance Goals	Aspirational signals of high and sustainable performance in alignment with our strategic intent.

Critical Enablers

DIGITAL TRANSFORMATION (DX)

Leveraging advances in digital in the pursuit of our goals

PATIENT CENTRICITY

Putting patients at the center of what we do

VALUE Gene*

Capability system to secure the path from innovation to VALUE

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

Reasons to engage in digital transformation

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

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Digital Transformation of Astellas Pharma

Shinya Suda
Senior Vice President, Information Systems

Shinya Suda

Senior Vice President, Information Systems

Brief Personal History

1992   Joined the former Yamanouchi Pharmaceutical (currently Astellas Pharma)

2004   In charge of IT Integration Secretariat of Merger Preparation Committee

2008   IT Division, UK Subsidiary

2011   Director, Corporate IT Division

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

Awards

2021   Forbes JAPAN CIO Award "Management Contribution Award"

Estimation of "digital technology utilization effects" by consulting firms

Drug R&D
Cost

Reduced by approx.
60%[1]

Drug R&D
Time

Reduced by approx.
2.4 years[1]

EBITDA*

Improved by
45 to 75%[2]

[1] Source: "Paradigm of New Drug Discovery through Technology Advance" (Deloitte Tohmatsu Consulting LLC)
  "With advances in (digital) technology, (omitted) it will be possible, 15 to 20 years from now, to reduce the cost of pharmaceutical research and
   development by about 60% and shorten the development period by about 2.4 years."
  https://www2.deloitte.com/jp/ja/pages/life-sciences-and-healthcare/articles/ls/brnp-v1.html

[2] Source: "How pharma can accelerate business impact from advanced analytics", McKinsey & Company
  "Advanced analytics could improve EBITDA for pharmaceutical companies by 45%-75%"
  https://www.mckinsey.com/industries/life-sciences/our-insights/how-pharma-can-accelerate-business-impact-from-advanced-analytics

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*Earnings before interest payments, tax depreciation, and amortization

Pharma is an information industry
1 - Handling massive amounts of data throughout the value chain

Drug discovery	Development	Manufacturing	Sales	Lifecycle management

Modality screening

Candidate modality optimization

Clinical trial data

Application documents

Monitoring of production process

Marketing/Supply chain management

Information provision/collection activities

Post-marketing surveillance/adverse drug reaction information

Enterprise business platform and analytics supporting data-driven management

Cybersecurity for secure data sharing and utilization

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Pharma is an information industry
2 - Handle massive amounts of data around the world

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

Established Markets *1

International Markets *3

Greater China *2

US

Japan

Astellas Pharma Europe B.V.
Meppel Plant

Astellas Pharma China, Inc.
Shenyang Plant

Astellas Pharma Ireland
Co., Limited
Kerry Plant

Astellas Pharma
Global Development, Inc.

Astellas China Investment Co., Limited

Toyama Technology Center
Takaoka Plant

Universal
Cells, Inc.

Iota Biosciences,Inc.

Astellas Gene Therapies

Astellas Venture
Management LLC
（San Francisco office）

Astellas Rx+ Business
Accelerator,LLC

Astellas Innovation
Management LLC
（San Francisco office）

Xyphos Biosciences,
Inc.

Astellas Institute for
Regenerative
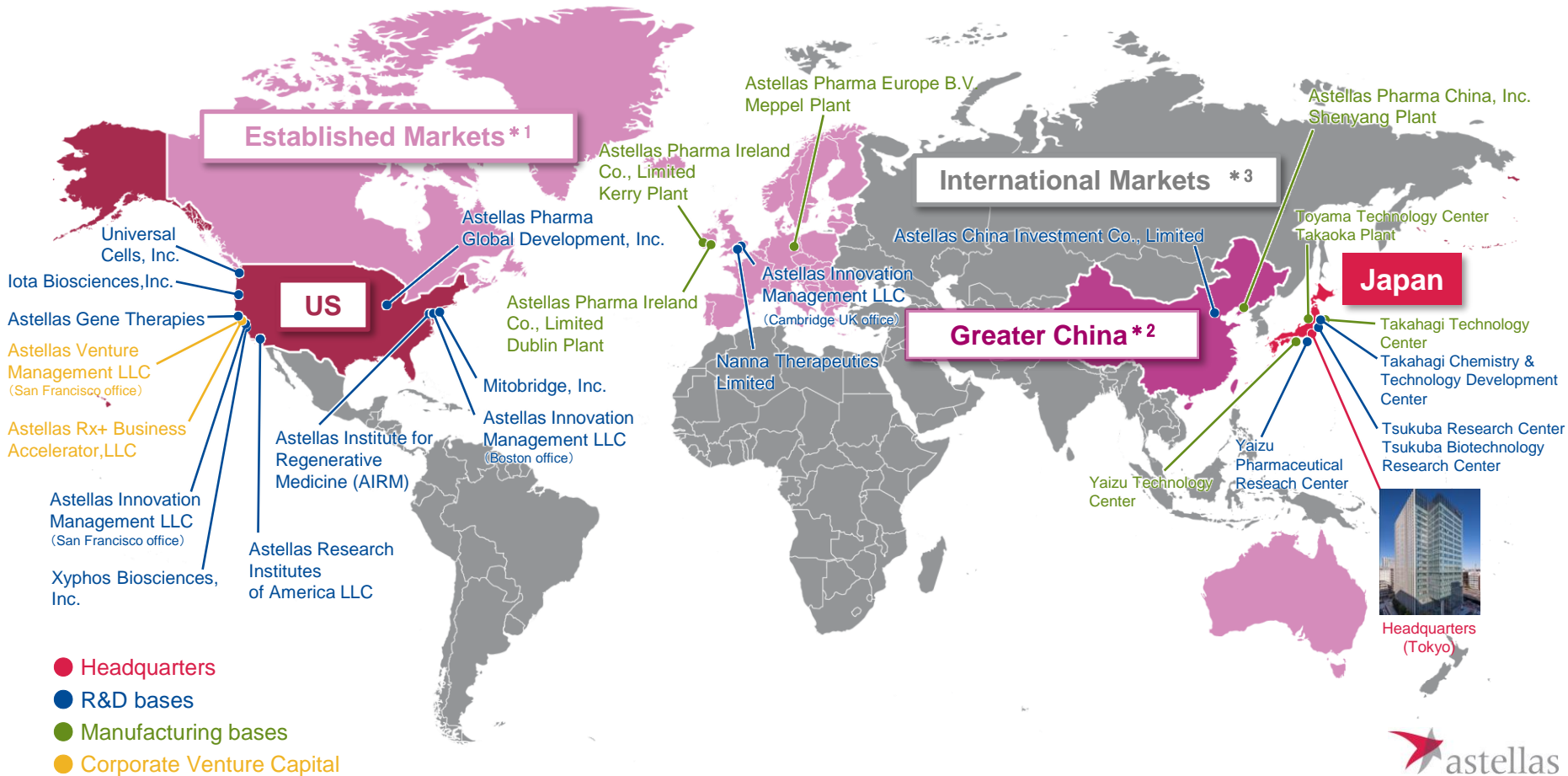Medicine (AIRM)

Astellas Research
Institutes
of America LLC

Astellas Pharma Ireland
Co., Limited
Dublin Plant

Mitobridge, Inc.

Astellas Innovation
Management LLC
（Boston office）

Astellas Innovation
Management LLC
（Cambridge UK office）

Nanna Therapeutics
Limited

Takahagi Technology
Center

Takahagi Chemistry &
Technology Development
Center

Tsukuba Research Center
Tsukuba Biotechnology
Research Center

Yaizu
Pharmaceutical
Reseach Center

Yaizu Technology
Center

Headquarters
(Tokyo)

- Headquarters
- R&D bases
- Manufacturing bases
- Corporate Venture Capital

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*1 Established Markets : Europe, Canada, Australia　*2 Greater China : China, Hong Kong, Taiwan　*3 International Markets　: Russia, Latin America, Middle East, Africa, South East Asia, South Asia, Korea
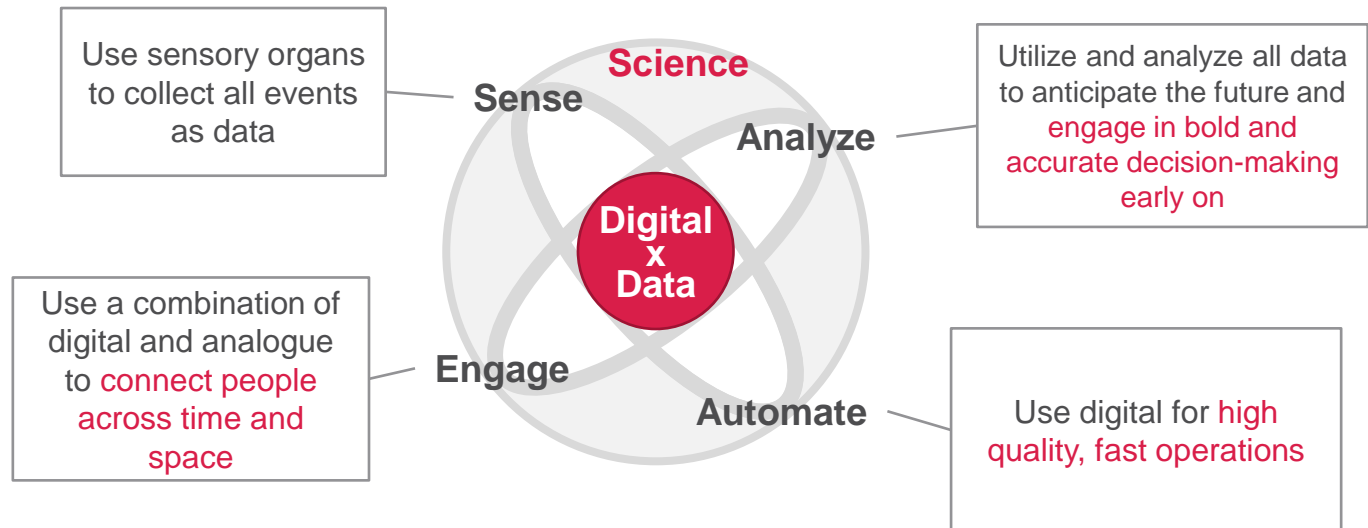
as of January 2022

DX Vision

Become a world-class Intelligent Enterprise that accelerates digital transformation to turn innovative science to VALUE for patients

Approach

- **Acquire competitive superiority by adding our company's accumulated knowledge of science to the 4 levers (sources of value) afforded by Digital × Data**
- **Best mix of people and digital**

Levers

Use sensory organs to collect all events as data

Science

Sense

Analyze

Utilize and analyze all data to anticipate the future and engage in bold and accurate decision-making early on

Digital
x
Data

Use a combination of digital and analogue to connect people across time and space

Engage

Automate

Use digital for high quality, fast operations

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Major divisions responsible for DX

Information Systems

- Promote business reform by introducing IT and digital technologies/solutions
- Continuously evolve the foundation for communication and data utilization

Transformation of existing operations
Renewal of digital infrastructure
(data analysis, AI utilization, workspace)

AIA*

- Data and advanced analytics experts
- Promote sophisticated data analysis and utilization of AI, machine learning and other advanced digital capabilities
- Identify new technologies and applications for advanced analytics

Advanced data analysis

Rx + Business Accelerator

- Create products and medical services that combine technologies and knowledge in different fields based on the strengths cultivated in the core prescription drug (Rx) business
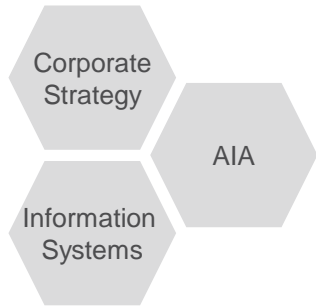
Establishment of new businesses

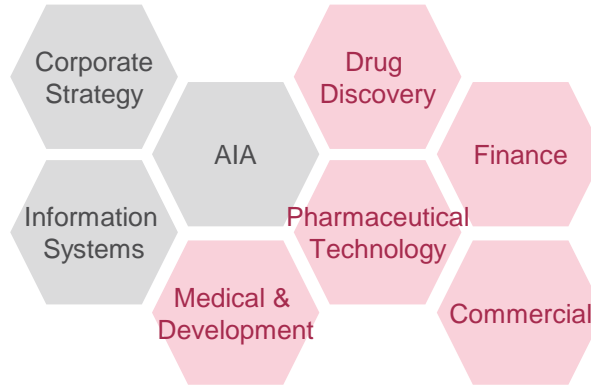**Transformation of existing businesses**

New businesses

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*Advanced Informatics & Analytics

Promotion system for DX

Center for Digital Insight

- Corporate Strategy
- AIA
- Information Systems

Digital Acceleration Committee

- Corporate Strategy
- Drug Discovery
- AIA
- Finance
- Information Systems
- Pharmaceutical Technology
- Medical & Development
- Commercial

FY18 — FY21 → CSP2021 Achievement
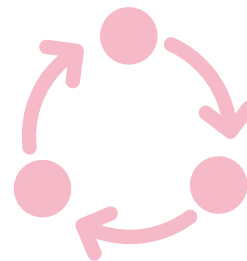
- Formulate strategy and vision
- Integrate roadmap
- Formulate investment prioritization policy

Implement strategic innovations

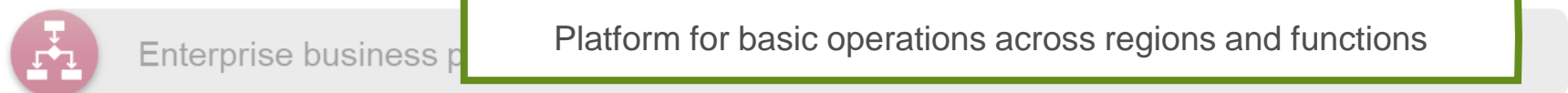Select priority investment items

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Cases presented today

Drug discovery	Development	Manufacturing	Sales	Lifecycle management
Drug discovery platform integrating humans × AI × robots	Decentralized clinical trials transforming the patient experience	Data mining to enable stable supply	Innovative digital channel development	Automation of pharmacovigilance activities

Modality screening

Candidate modality optimization

Clinical trial data

Application documents

Monitoring of production process

Marketing/Supply chain management

Information provision/collection activities

Post-marketing surveillance/adverse drug reaction information

Enterprise business p —— **Platform for basic operations across regions and functions**

Cybersecurity for secure da —— **Next-generation cybersecurity**

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- The more compounds are evaluated, the higher the likelihood of obtaining "compounds that readily bind to targets and exhibit robust pharmacological effects"[1,2]

→ Forecasting through high-speed, large-volume calculation is a prerequisite for finding good candidate compounds

	Conventional environment	Environment currently under consideration
Number evaluated	Millions	**Hundreds of millions**
Calculation environment	In-house server	**Cloud** Amazon Web Service × **AI** Machine Learning

Enormous number of candidate compounds

Simulation of bindability

Target molecules that cause diseases
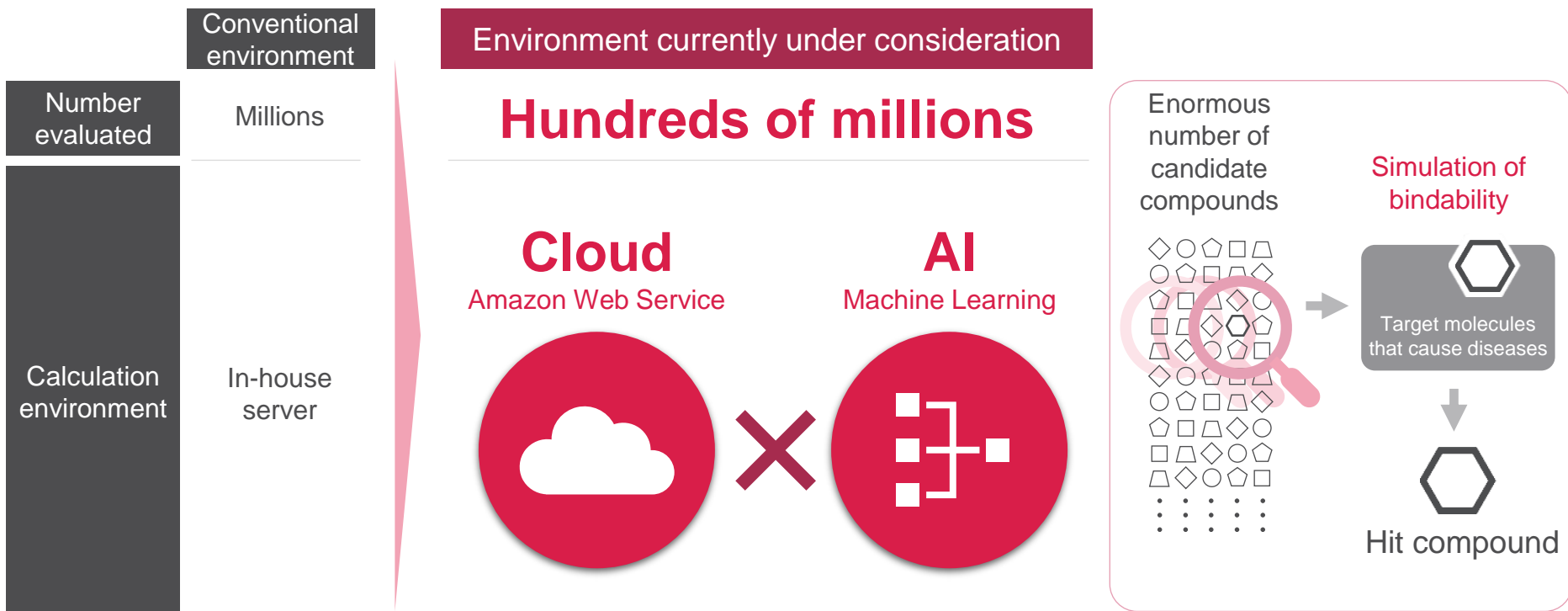
Hit compound

1 to 2 years of calculation in the conventional environment
➡ As short as 1 to 2 weeks in the new environment

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

"Human-in-the-Loop" drug discovery platform integrating humans × AI × robots

Researcher

Hit compounds
identified through
compound screening, etc.

(including issues with activity
and pharmacokinetics)

**Drug candidate
compounds**

AI for predicting
compound characteristics

Compound design AI

AI examines tens of thousands of
candidates to make proposals ranked
according to a uniqueness score

Automatic
preparation of lists of
experiment results

Analyze | Design

Test | Make

Cost IP Milestone
Speed FTE etc.

Comprehensive
judgment of researcher

Cell assay by AI × robot *

Automatic synthesis by robot

Shorten the time from hit compound to drug candidate compound **by as much as 70%**

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

World's only "Mahol-A-Ba" cellular drug discovery platform

- Research on iPS cells requires the "expert skills" of experienced researchers: *technique* and *powers of observation*
- Human resources for iPS cell research are limited, and this is one of the bottlenecks in research
- → Acceleration of research through researcher × AI × robot collaboration

	Past	Current
# Samples	>10	**>1,000 ~ >10,000**
Experiment	Manual	**"Mahol-A-Ba"**

"Expert arm" robot
Maholo
2017.11~

AI
Machine Learning

"Expert eye" robot
Astellas unique system*
2019.3~
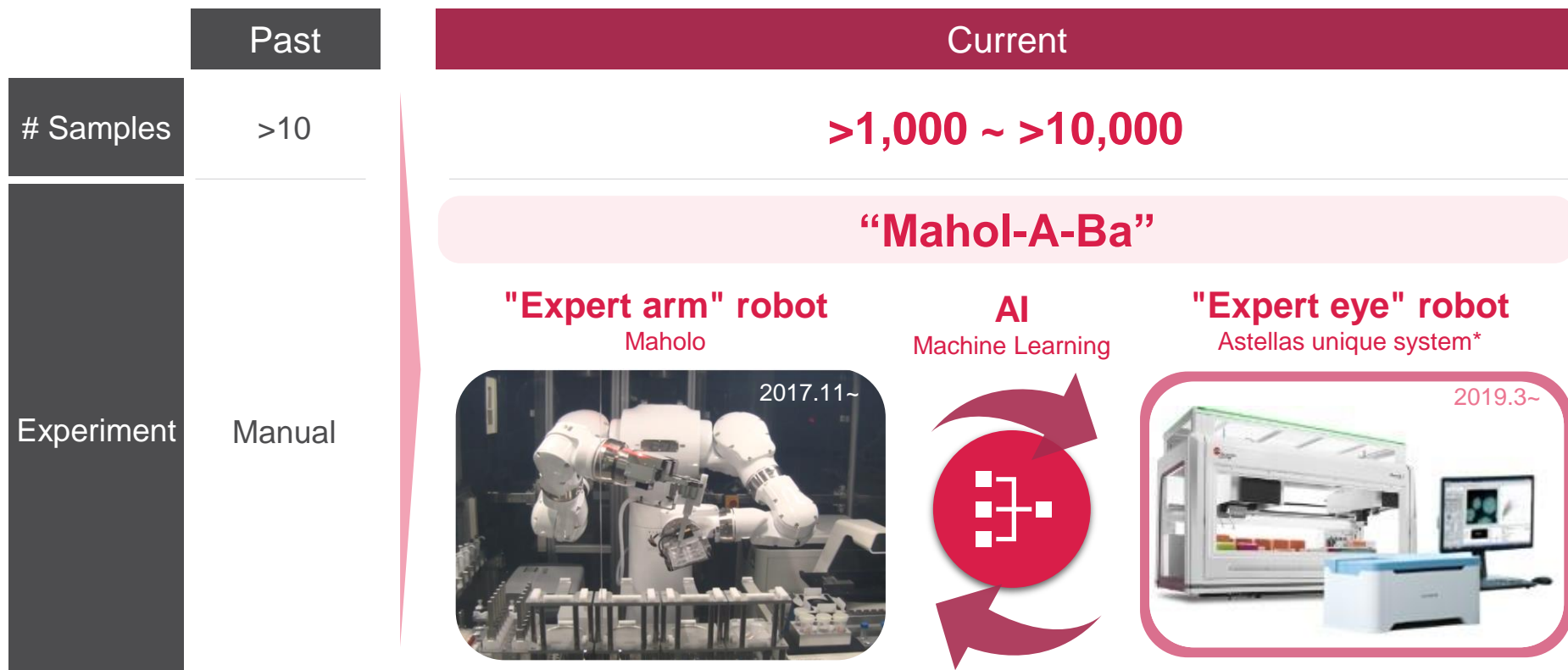
Conduct experiments at **100 ~ 1000 times** the scale
with **precision** and **reproducibility** as good or better than a human expert

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

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

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

Image of communication on clinical trials for muscle diseases

Healthcare professional

Let's evaluate your mobility in a fixed set of movements at a hospital.

Patient

Isn't there some way you could evaluate the improvement in my activities of daily living, too?

Healthcare professional
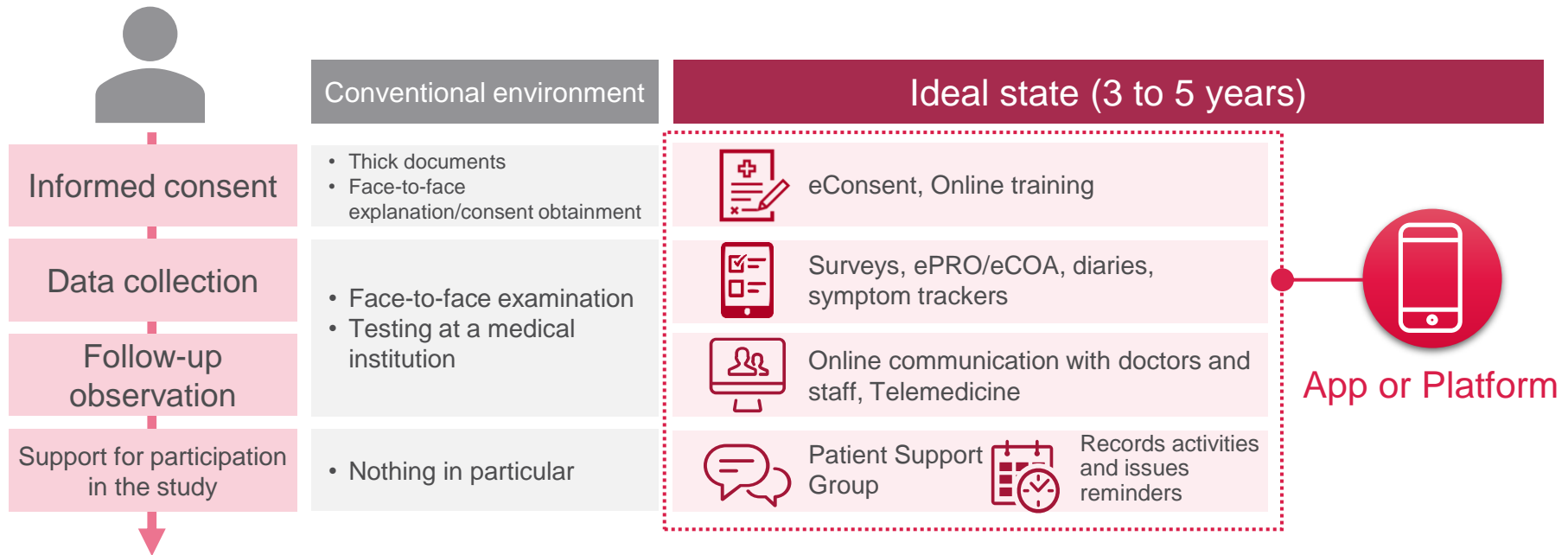
Can you travel to a distant site?

Patient

I cannot do without my medical device, but the airlines place restrictions on what can be carried on.

In some cases, I need a medical certificate from a doctor.

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

	Conventional environment	Ideal state (3 to 5 years)	
Informed consent	• Thick documents • Face-to-face explanation/consent obtainment	eConsent, Online training	
Data collection	• Face-to-face examination • Testing at a medical institution	Surveys, ePRO/eCOA, diaries, symptom trackers	**App or Platform**
Follow-up observation		Online communication with doctors and staff, Telemedicine	
Support for participation in the study	• Nothing in particular	Patient Support Group · Records activities and issues reminders	

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

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

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

Examples of digital use in ASP0367 US clinical trials

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

Informed consent

Data collection

Follow-up observation

Support for participation in the study

Video Assessment
Using a smartphone to record images of the patient engaging in activities of daily living, such as walking and eating
→ Analyzed remotely by central reviewer

e-Diary
Records of daily activities, such as whether the patient went out or stayed home all day

Wearable device
Obtain data on amount of activity

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Background of DCT's attention

Issue: "hospital visits" and "confinement time"

Important factors in study participation (US)[1]
- Location of medical institution   60%
- Visit interval   49.5%

What aspects of taking part in the study were inconvenient? (Japan)[2]
- The burden of confinement time
  23.4% (1st place)
- The burden of hospital visits
  22.3% (2nd place)

Effects of enhancing patient engagement[3]

More convenient participation in studies
- Retention rate   30–40% increase
- Study timeline   20–35% reduction

Plain language clinical trial results
- Recruitment rate   15–20% increase
- Retention rate   40–50% increase

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Source: 1. Anderson A et al., Global Public Attitudes About Clinical Research and Patient Experiences With Clinical Trials, JAMA Netw Open. 2018 Oct; 1(6).
2. Soyoku Nobeyama, "わが国における治験実態および患者満足度調査", THERAPEUTIC RESEARCH 2019 40（12）961-80.
3. Expansion of Expected Net Present Value Framework for Evaluating Patient Engagement Methods Clinical Trials Transformation Initiative (CTTI)

- It is the mission of a pharmaceutical company to maintain a stable supply of drugs to patients.
- Quality and production issues have a critical impact on patients' health and result in loss of social trust in the company

→ Increase the sophistication of manufacturing in order to continue delivering better quality drugs to patients

"DAIMON"

The only technology that applies cutting-edge data management and analysis to the manufacturing site for pharmaceutical products
(Start of review in 2013, start of development in 2015, implementation in 2018)

Understanding products and production processes

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

Preparedness for dealing with quality and production issues

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

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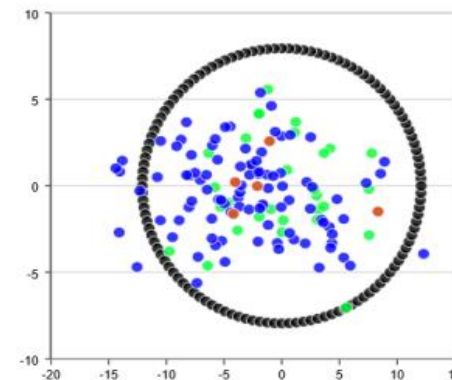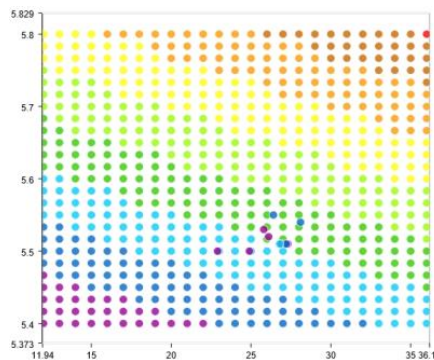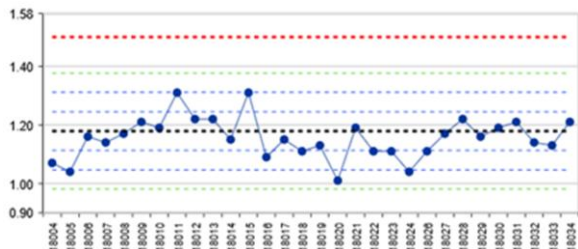
Multivariate monitoring
Unknown relationships

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

Cause and effect and regression monitoring
### Known relationships

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

Univariate monitoring
All data

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

All manufacturing has a common essence, regardless of modality
→ Apply the systems and extensive knowledge gained
with small molecules **to biopharmaceuticals as well**

Examples of challenges for innovation in pharmaceutical manufacturing
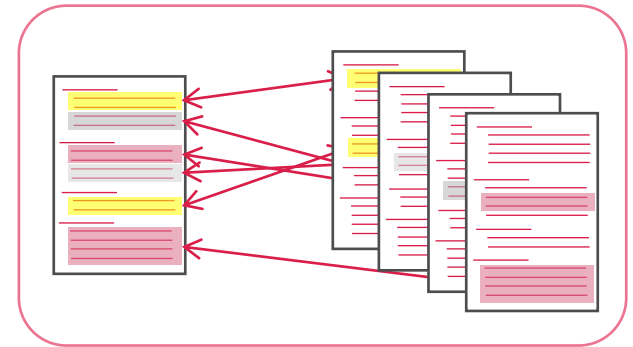
Training on aseptic operation
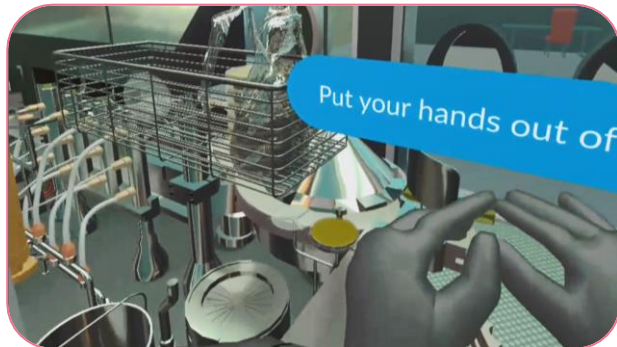
MR
(Mixed Reality)

Support for checking consistency between documents

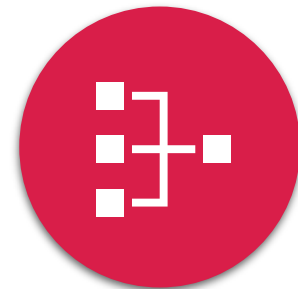Put your hands out of

VR
(Virtual Reality)

Manufacturing Operation Support

AI
Natural Language Processing

Various studies underway or completed
CMO collaboration support tools, VR plant tours, automated cell culture, etc.

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Omni-channel communication to revolutionize the customer experience

- Properly providing information to healthcare professionals and collecting information from them is an essential part of contributing to the treatment of patients.

→ Use digital channels to pursue timely and appropriate provision of information

Healthcare professionals

MR*, MSL**

MR, MSL in remote

Chatbot

Owned Media

Email
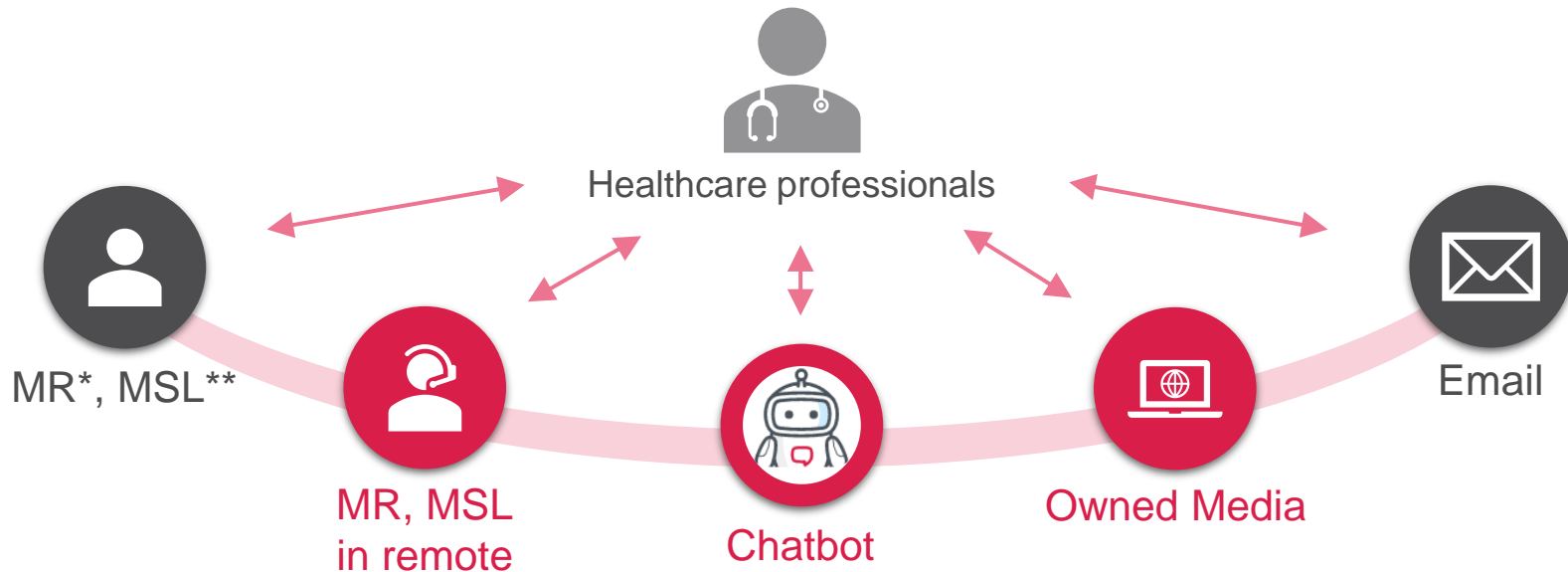
"Astellas Online MR"
- Started in Japan in June 2021
- Activities to provide and collect highly specialized information are now ongoing for 6 products in 4 areas.

"Collabot"
- Chatbot-based information provision services for some products have been provided in several global regions since 2020.
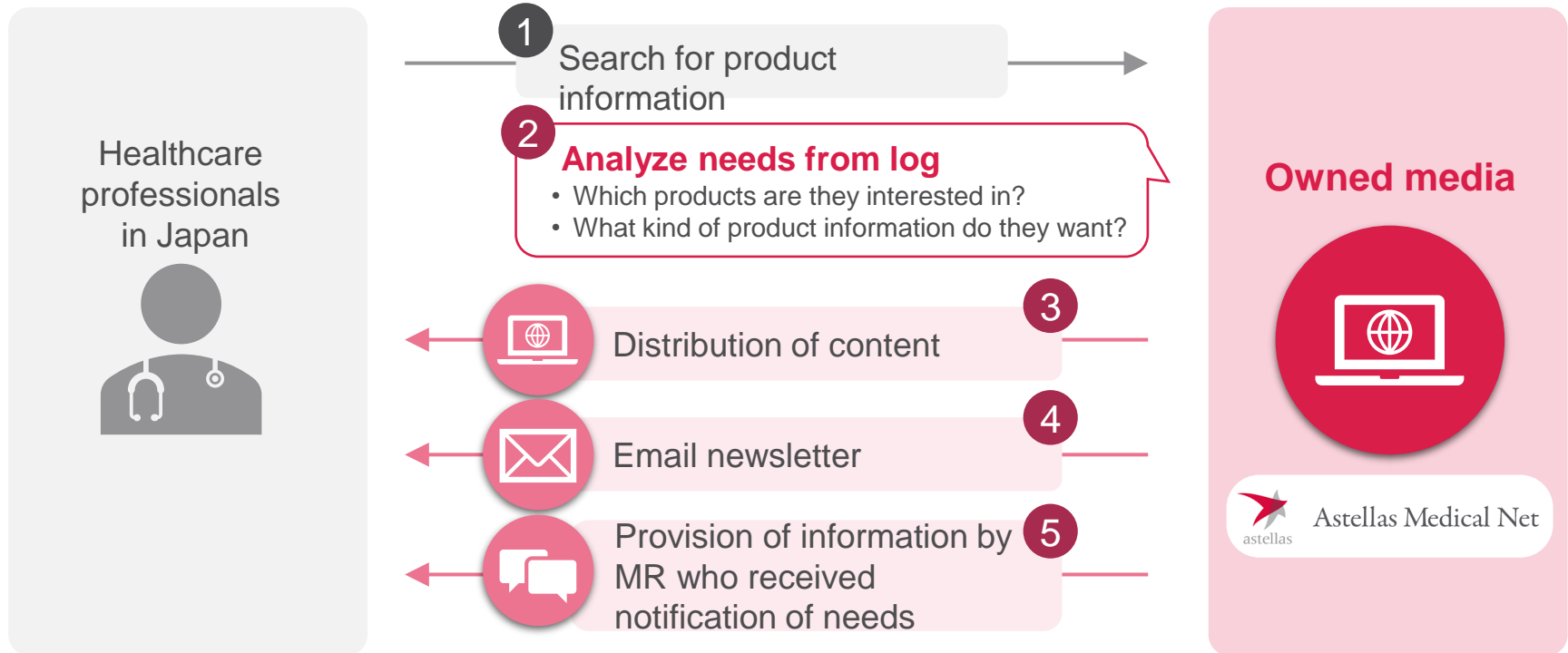
*MR: Medical Representative
**MSL: Medical Science Liaison

Omni-channel communication to revolutionize the customer experience

- The information that is delivered does not tell the doctor anything new, so the doctor must search for the needed information himself
→ Use channels skillfully to deliver "the information that the doctor wants", not the "information you want to communicate to the doctor"

Healthcare professionals in Japan

1 Search for product information

2 Analyze needs from log
- Which products are they interested in?
- What kind of product information do they want?

3 Distribution of content

4 Email newsletter

5 Provision of information by MR who received notification of needs

Owned media

Astellas Medical Net

Number of visitors increased by **31%**, number of views of web symposium page increased by **117%**, etc. *

*Calculated based on Adobe Analytics aggregated data from September 2020 to October 2021

Development of an advanced method for providing information via the metaverse

- Progress has been made in the transition to online communication unrestricted by place or time
- On the other hand, we cannot fully demonstrate the "benefits of two-way and face-to-face communication" in the current environment

→ **Aiming to realize completely new two-way communication with healthcare professionals**

Metaverse/XR

Phase 1

Seminars/lectures in virtual space

- Higher quality of communication, including casual exchanges of information between participants

Phase 2

Fusion of virtual and real

- Enable free communication between venue participants and online participants
- Conceptual stage

Phase 1 pilot to start in January 2022

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Automation of pharmacovigilance activities

- Adverse event (AE) information is reported 24/7 from patients and healthcare professionals around the world.
- AE information collected must be entered into a safety database for assessment, monitoring, reporting to regulatory authorities, and planning of safety measures.

→ Automate capturing and processing of vast amounts of information, which could further contribute to patient safety

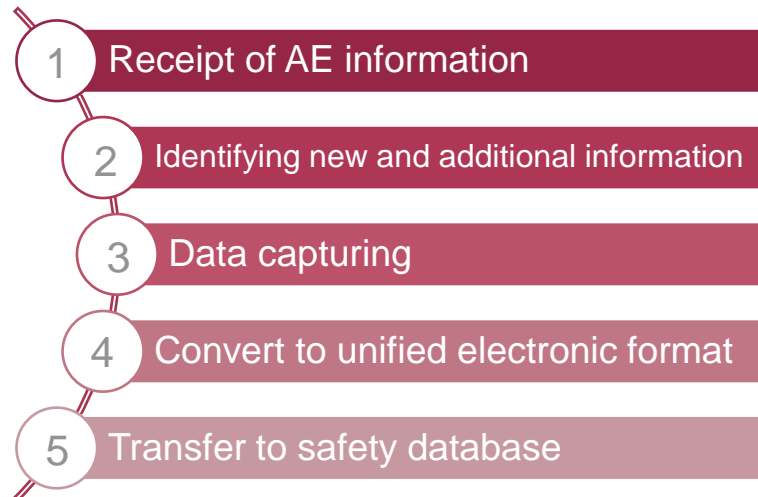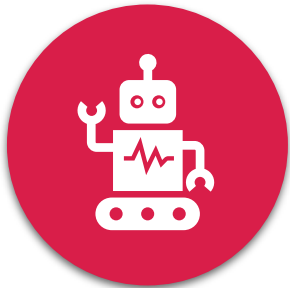*Phase1*

AE info. Capture, Case Intake	Medical Review	Workflow & Case Processing Enhancements	Risk Mgmt., Signal Detection	Compliance Reporting

AI, RPA, etc.

1. Receipt of AE information
2. Identifying new and additional information
3. Data capturing
4. Convert to unified electronic format
5. Transfer to safety database

- A single point of entry for information

- Labor saving of data entry
- Minimize data entry errors
- Shorten processing time

Expected cost savings of several hundred million yen per year when the entire system is operational in 5 years.

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

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

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

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

Goals of "Apple" platform (examples)

- **Creating a real-time dashboard showing "accounting information" and "product inventory and demand" around the world**
  - → Development of high-precision plans and strategies for finance, procurement, production, and marketing; support for management decisions
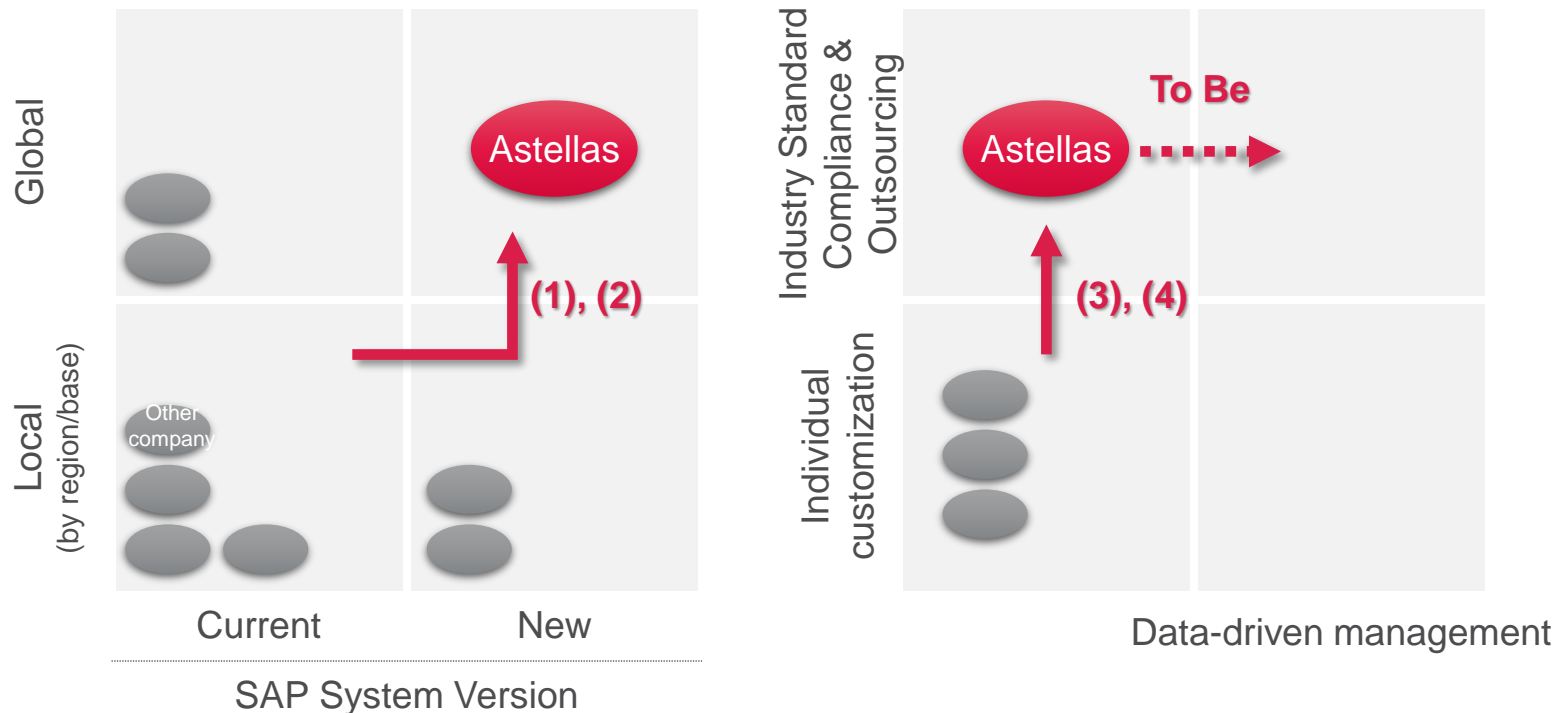

image

Grasp all sorts of information from throughout the world and use it to power innovation in Astellas businesses

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

- A core business system based on the SAP system has been established, implemented, and transferred to the cloud
- Astellas is one of the few pharmaceutical companies worldwide that have implemented all of the following at once and completed their introduction to the three main regions
  (1) SAP version upgrade, (2) global integration, (3) industry standard compliance, (4) outsourcing

Global

Local
(by region/base)

Other
company

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(1), (2)

Current   New

SAP System Version

Industry Standard
Compliance &
Outsourcing

Individual
customization

Astellas   To Be

(3), (4)
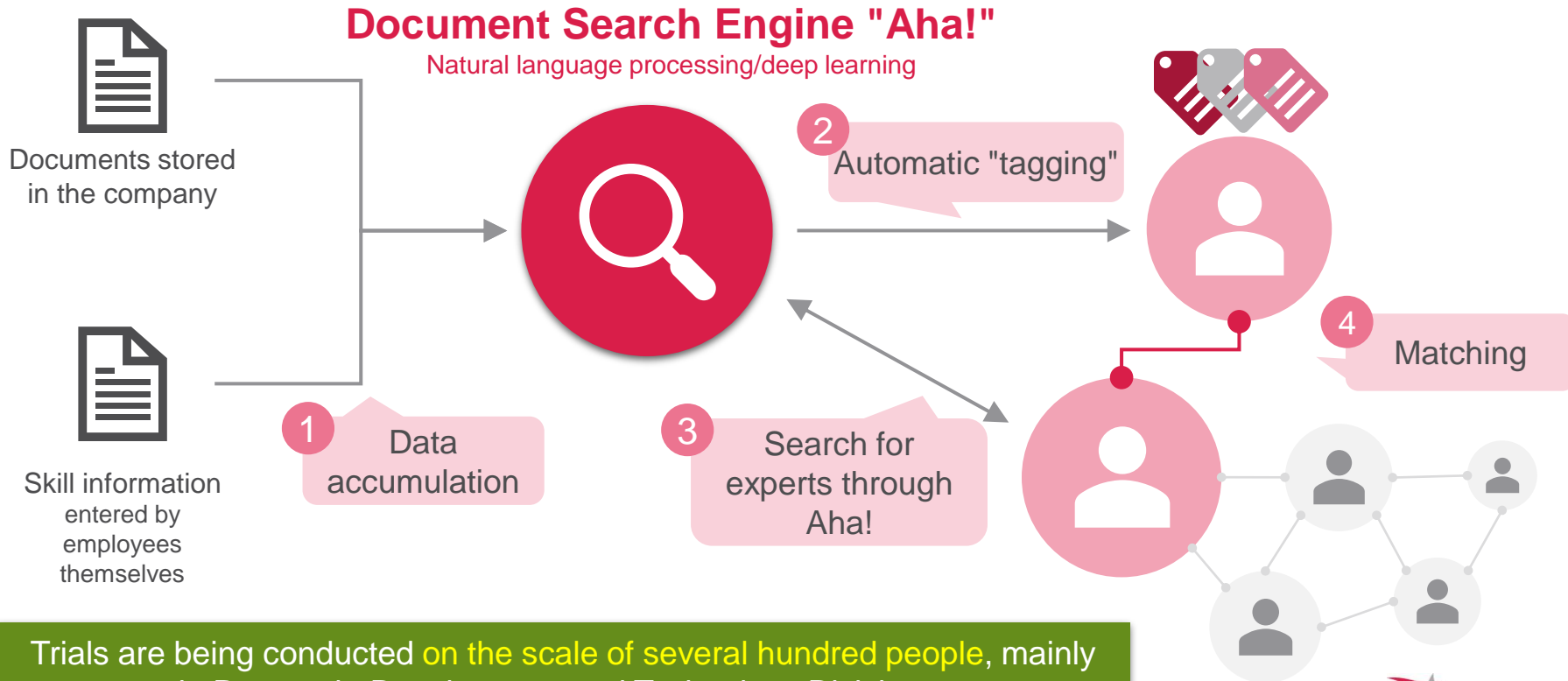
Data-driven management

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

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Internal Talent Search System "TAKUMI"

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

Document Search Engine "Aha!"
Natural language processing/deep learning

Documents stored in the company

Skill information entered by employees themselves

1 Data accumulation

2 Automatic "tagging"
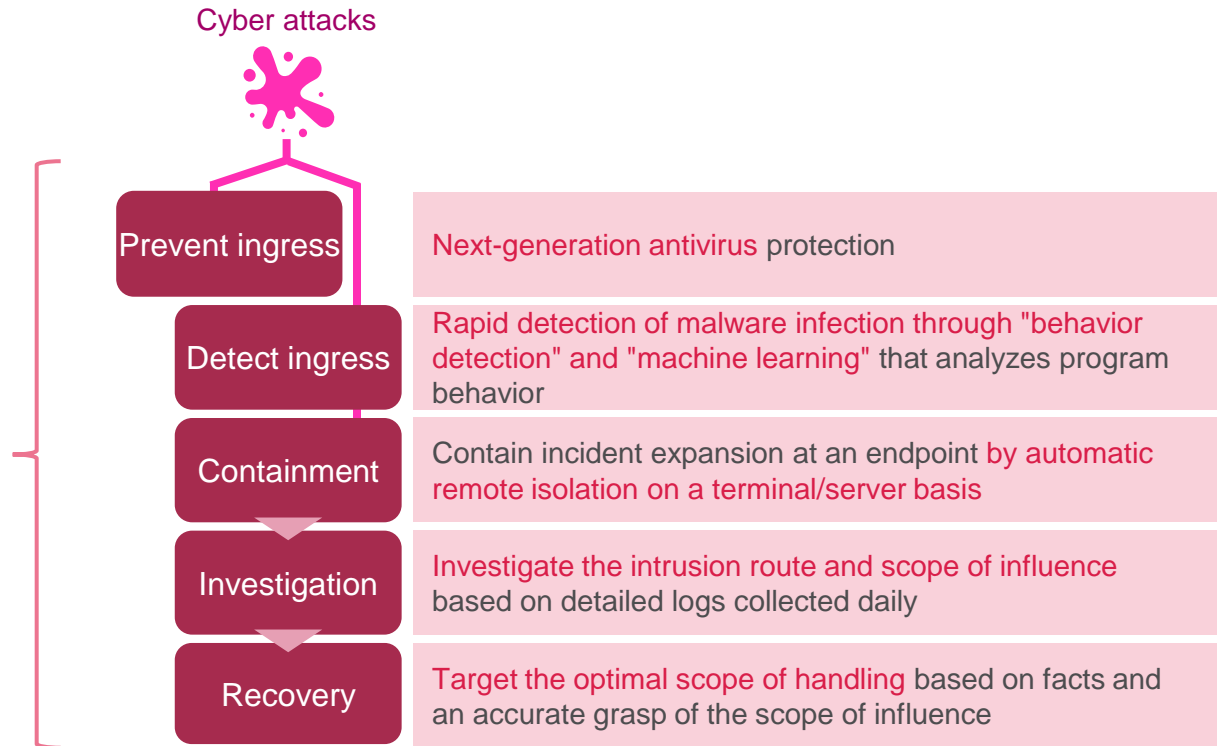
3 Search for experts through Aha!

4 Matching

Trials are being conducted on the scale of several hundred people, mainly in Research, Development and Technology Divisions.

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"Protection" DX: cybersecurity

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

Cyber attacks

EDR
(Endpoint Detection and Response)

Prevent ingress	Next-generation antivirus protection
Detect ingress	Rapid detection of malware infection through "behavior detection" and "machine learning" that analyzes program behavior
Containment	Contain incident expansion at an endpoint by automatic remote isolation on a terminal/server basis
Investigation	Investigate the intrusion route and scope of influence based on detailed logs collected daily
Recovery	Target the optimal scope of handling based on facts and an accurate grasp of the scope of influence

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

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DX Vision

Become a world-class Intelligent Enterprise that accelerates digital transformation to turn innovative science to VALUE for patients

Approach

- **Acquire competitive superiority by adding our company's accumulated knowledge of science to the 4 levers (sources of value) afforded by Digital × Data**
- **Best mix of people and digital**

Levers

Use sensory organs to collect all events as data

Science

Sense

Analyze

Utilize and analyze all data to anticipate the future and engage in bold and accurate decision-making early on

Digital x Data

Use a combination of digital and analogue to connect people across time and space

Engage

Automate

Use digital for high quality, fast operations

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