DIGITAL TRANSFORMATION OF ASTELLAS PHARMA

Media Briefing - January 21, 2022
Cautionary Statement Regarding Forward-Looking Information

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
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
Definition of VALUE

Common Definition of VALUE *

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

Definition of VALUE

Common Definition of VALUE *

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

Outcomes

Double
Outcomes

Cost

Triple
Cost

Double
the VALUE

One third
the cost

Triple
the VALUE

Reasons to engage in digital transformation

### Corporate Strategic Plan 2021

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>Strategic Goals</td>
<td>Our evolving strategic path and priorities, detailed to bridge effectively to execution.</td>
</tr>
<tr>
<td>Organizational Health Goals</td>
<td>The internal environment that will unlock our full potential to innovate and execute.</td>
</tr>
<tr>
<td>Performance Goals</td>
<td>Aspirational signals of high and sustainable performance in alignment with our strategic intent.</td>
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**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

<table>
<thead>
<tr>
<th>Ideal state of management</th>
<th>Data-driven management</th>
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<tbody>
<tr>
<td><strong>DX roles</strong></td>
<td>Provide innovative technologies, AI, robotics, and platforms that will revolutionize the way solutions are designed, created, tested, and analyzed</td>
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<tr>
<td><strong>DX effects</strong></td>
<td>Creating New VALUE</td>
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<td></td>
<td>Increased Productivity</td>
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<td></td>
<td>Preparing for Risk</td>
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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”
Impact of Digital Transformation (DX) on the Pharmaceutical Industry

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 years¹

- **EBITDA**
  - Improved by 45 to 75%²

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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."


² Source: “How pharma can accelerate business impact from advanced analytics”, McKinsey & Company

"Advanced analytics could improve EBITDA for pharmaceutical companies by 45%-75%"


*Earnings before interest payments, tax depreciation, and amortization
Pharma is an information industry
1 - Handling massive amounts of data throughout the value chain

<table>
<thead>
<tr>
<th>Drug discovery</th>
<th>Development</th>
<th>Manufacturing</th>
<th>Sales</th>
<th>Lifecycle management</th>
</tr>
</thead>
<tbody>
<tr>
<td>Modality screening</td>
<td>Clinical trial data</td>
<td>Application documents</td>
<td>Marketing/Supply chain management</td>
<td>Post-marketing surveillance/adverse drug reaction information</td>
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<tr>
<td>Candidate modality optimization</td>
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<td></td>
<td>Monitoring of production process</td>
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<tr>
<td></td>
<td>Information provision/collection activities</td>
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</table>

Enterprise business platform and analytics supporting data-driven management

Cybersecurity for secure data sharing and utilization
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**
- US
- Europe
- Canada
- Australia
- Greater China: China, Hong Kong, Taiwan
- International Markets: Russia, Latin America, Middle East, Africa, South East Asia, South Asia, Korea

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

*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
Digital Ambition in 2025

**DX Vision**

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

- 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

**Approach**

**Levers**

- Use sensory organs to collect all events as data
- Use a combination of digital and analogue to connect people across time and space
- Utilize and analyze all data to anticipate the future and engage in bold and accurate decision-making early on
- Use digital for high quality, fast operations
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

**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

**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

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

Advanced data analysis

Establishment of new businesses

Transformation of existing businesses

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*Advanced Informatics & Analytics*
Promotion system for DX

Center for Digital Insight

Digital Acceleration Committee

- Formulate strategy and vision
- Integrate roadmap
- Formulate investment prioritization policy

Implement strategic innovations

Select priority investment items

CSP2021 Achievement
Cases presented today

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

Platform for basic operations across regions and functions

Next-generation cybersecurity
Ultra-large-scale virtual screening

- 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

<table>
<thead>
<tr>
<th>Environment currently under consideration</th>
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<tbody>
<tr>
<td><strong>Conventional environment</strong></td>
</tr>
<tr>
<td>Number evaluated</td>
</tr>
<tr>
<td>Millions</td>
</tr>
<tr>
<td>Calculation environment</td>
</tr>
<tr>
<td>In-house server</td>
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</tbody>
</table>

**Hundreds of millions**

- Cloud Amazon Web Service
- AI Machine Learning

1 to 2 years of calculation in the conventional environment

→ As short as 1 to 2 weeks in the new environment

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 \(\times\) AI \(\times\) robots

Hit compounds identified through compound screening, etc. (including issues with activity and pharmacokinetics)

Drug candidate compounds

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

*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

<table>
<thead>
<tr>
<th>Past</th>
<th>Current</th>
</tr>
</thead>
<tbody>
<tr>
<td># Samples</td>
<td>&gt;10</td>
</tr>
<tr>
<td>Experiment</td>
<td>Manual</td>
</tr>
<tr>
<td>Current</td>
<td>&gt;1,000 ~ &gt;10,000</td>
</tr>
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</table>

“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

- Informed consent
  - Thick documents
  - Face-to-face explanation/consent obtainment

- Data collection
  - Face-to-face examination
  - Testing at a medical institution

- Follow-up observation
  - Nothing in particular

- Support for participation in the study

Ideal state (3 to 5 years)

- eConsent, Online training
- Surveys, ePRO/eCOA, diaries, symptom trackers
- Online communication with doctors and staff, Telemedicine
- Patient Support Group
- Records activities and issues reminders

App or Platform

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

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
### Background of DCT's attention

**Issue: “hospital visits” and “confinement time”**

#### Important factors in study participation (US)
- Location of medical institution: 60%
- Visit interval: 49.5%

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

### Effects of enhancing patient engagement

#### 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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Our own data mining system for manufacturing: "DAIMON"

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

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

⇒ Increase the sophistication of manufacturing in order to continue delivering better quality drugs to patients
Our own data mining system for manufacturing: "DAIMON"

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

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.)

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)

Unknown relationships

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

Multivariate monitoring

Cause and effect and regression monitoring
Examples of challenges for innovation in pharmaceutical manufacturing

Training on aseptic operation

VR (Virtual Reality)

MR (Mixed Reality)

Support for checking consistency between documents

AI

Natural Language Processing

Manufacturing Operation Support

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

"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

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
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

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

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

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

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

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

**EDR**
(Endpoint Detection and Response)

- Prevent ingress
- Detect ingress
- Containment
- Investigation
- Recovery

**Next-generation antivirus protection**
Rapid detection of malware infection through "behavior detection" and "machine learning" that analyzes program behavior

Contain incident expansion at an endpoint by automatic remote isolation on a terminal/server basis

Investigate the intrusion route and scope of influence based on detailed logs collected daily

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.
Digital Ambition in 2025

**DX Vision**

**Approach**

**Levers**

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

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

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- Utilize and analyze all data to anticipate the future and engage in bold and accurate decision-making early on
- Use digital for high quality, fast operations