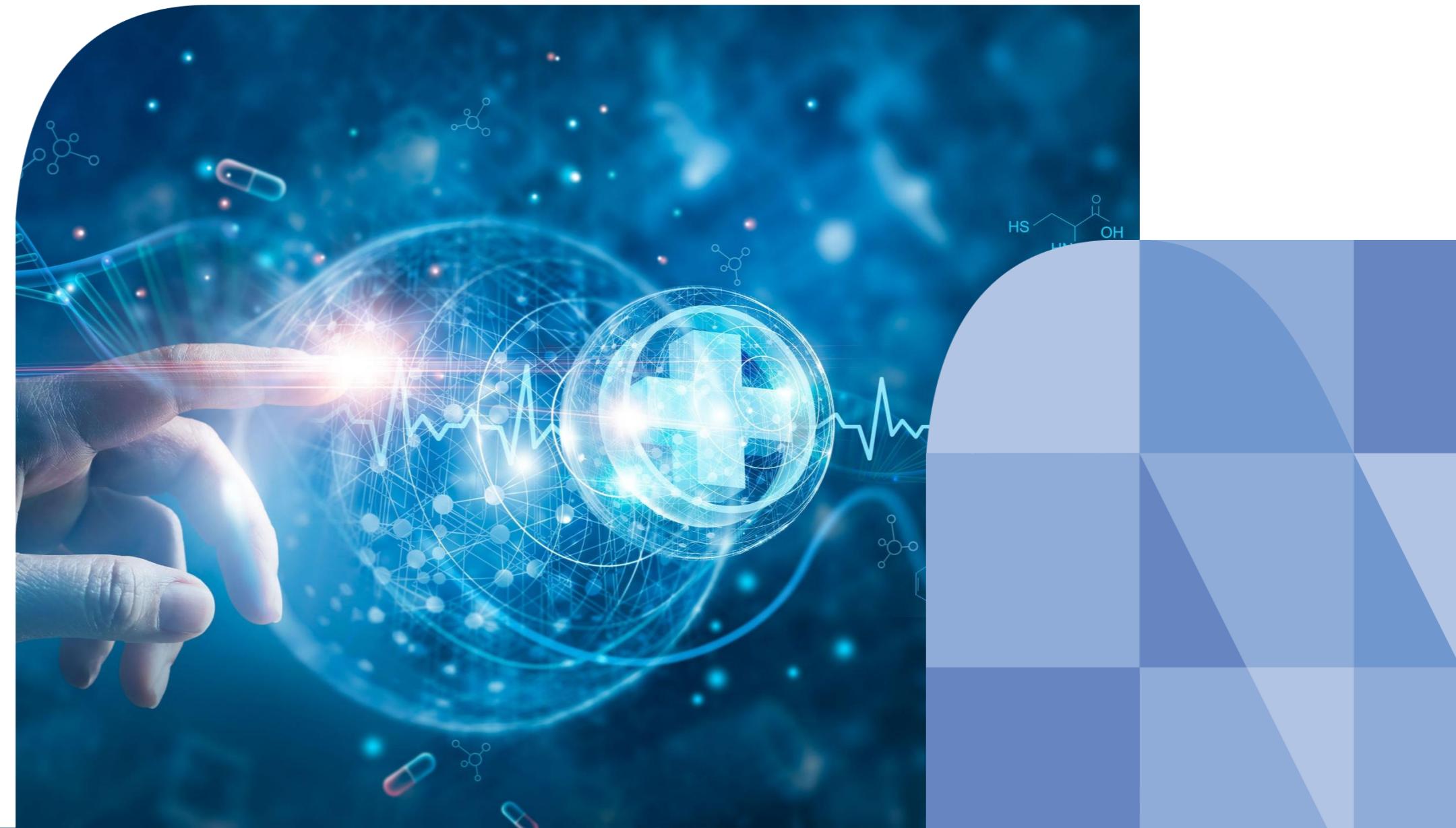


# The Future of Drug Discovery Envisioned by NTT DATA

Ultrafast Drug Discovery Research Cycle Achieved Through Digitalization



# Mission



## Pharmaceutical Companies' New Approach to Drug Discovery Under the Changing Environment and Rising Tide of Digitalization

In its role as a pharmaceutical company working toward innovation in patient experience of patient-centered care (MX), NTT DATA aims to **achieve an ultrafast drug discovery cycle** as its mainline approach toward digital transformation (DX).

Digital technology has been transforming business in all industries in recent years and the pharmaceutical industry is no exception to this trend.

Every year, drug discovery is becoming increasingly challenging and research and development (R&D) costs in the pharmaceutical industry are among the highest of all major industries. Ongoing changes include regulations on the activities of medical sales representatives (MRS) as well as NHI price revisions that have been transforming the value chains of pharmaceutical companies with each passing year. Meanwhile, information technology (IT) companies like GAFA and startups with high levels of technological competence are actively entering the healthcare and pharmaceutical industry by taking advantage of their technological, information – gathering, and analytical capabilities. Such trends have driven the redefining of industry players and value chains and are rapidly accelerating change.

In light of these circumstances, we believe that it is time to turn our attention once again to drug discovery , the true source of value creation as a pharmaceutical company. Transforming drug discovery through digital technology will lead to innovation in MX and the creation of new value as a pharmaceutical company. While there have been many approaches taken to DX in business, we believe that speeding up the drug discovery cycle is the key to discovering new drugs, and that this goal will require the digital twinning of drug discovery.

Digital twinning, in which all real-world activities in drug discovery are recorded and stored in a digital space, will accelerate the drug discovery cycle and achieve a data-driven PDCA cycle. The transformation of the drug discovery research process through digitalization will not only improve the efficiency of drug discovery but also achieve more creative and innovative drug discovery.

Drawing on its know-how and technological capabilities acquired over the years, NTT DATA will design a new drug discovery process for the pharmaceutical industry together with our clients. Our unique assets will then lead us from first giving shape to this design to then implementing it in an integrated and consistent approach that builds a new **future of drug discovery**.

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# Chapter 1

## Changing Environment and Digitalization in Drug Discovery



# Growing Importance of Drug Discovery and Trend Toward Digitalization

## Circumstances and Challenges Surrounding the Pharmaceutical Industry

Currently, the environment for Japanese pharmaceutical companies to engage in drug discovery is becoming more and more severe. The increasingly diverse modalities<sup>\*1</sup> including biologics and complex target selection have made drug discovery even more challenging, causing a continued rise in the costs required for drug discovery.

Despite the large amount of time and money required for drug discovery research, the probability of success is said to be only 1 in 30,000.<sup>\*2</sup> On the other hand, repeated reductions in NHI drug prices to control rising healthcare costs among the aging population have made it difficult to generate profits from drug discovery. The challenge in surviving under such circumstances will be how we can find the most effective way to invest in R&D. <sup>\*3</sup>

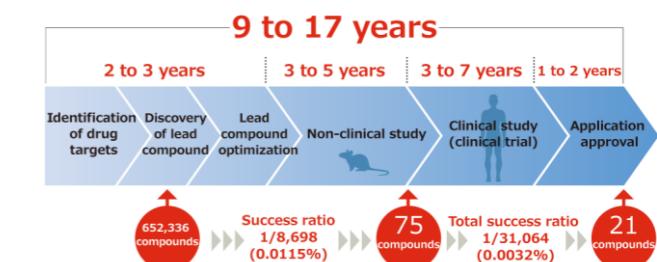
## Importance of Research in R&D

The growing importance of the research phase of R&D once again looms before us as the key to staying competitive in drug discovery research phase and achieving further expansion in value creation.

In general, drug discovery requires 9 to 17 years. This includes 2 to 3 years for drug discovery research and 3 to 7 years for clinical trials which is the longest phase.<sup>\*4</sup>

Drug discovery involves enormous costs as we progress from the research phase to the clinical trial phase, and failure in clinical trials can result in significant financial loss for a pharmaceutical company. Therefore, along with efforts to improve the efficiency of clinical trials through the use of IT and real-world data (RWD), it is essential that we identify those drug targets with the highest degree of potential contribution to the treatment of the target disease and the highest probability of success in the research phase, and then quickly generate a compound with superior efficacy and safety, thus increasing the probability of successful

clinical trials.



Source: Japan Pharmaceutical Manufacturers Association "Submitted material in the 1st Drug Development Conference"  
<https://www.kantei.go.jp/jp/singi/kenkouryou/iyakuhin/dai1/siryou2-5.pdf>

<sup>\*1</sup> Modalities: Classification of drug discovery means such as small molecules and antibody drugs.

<sup>\*2</sup> Source: Japan Pharmaceutical Manufacturers Association. DATA BOOK 2022.  
[https://www.jpma.or.jp/news\\_room/issue/databook/ja/lofurc000000ybyo-att/DATABOOK2022\\_J\\_ALL.pdf](https://www.jpma.or.jp/news_room/issue/databook/ja/lofurc000000ybyo-att/DATABOOK2022_J_ALL.pdf)

<sup>\*3</sup> Source: Ministry of Health, Labour and Welfare. *Toward the Development of a Vision for the Pharmaceutical Industry*.  
<https://www.mhlw.go.jp/content/10807000/000780122.pdf>

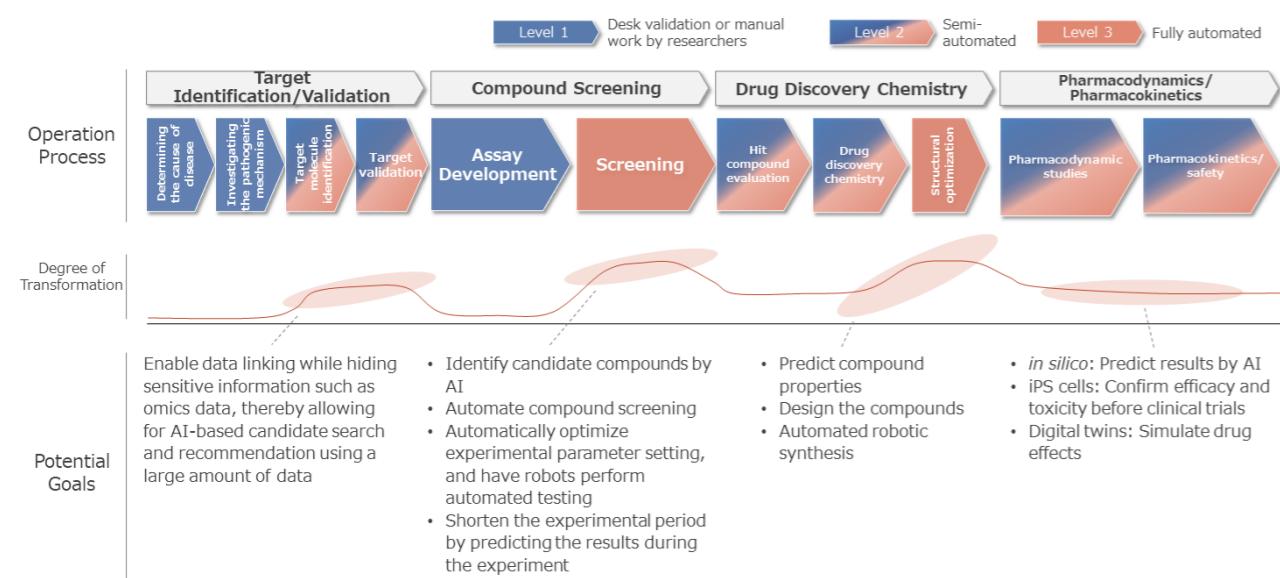
<sup>\*4</sup> Source: Japan Pharmaceutical Manufacturers Association. Q33. How long does it take to develop one drug?  
[https://www.jpma.or.jp/about\\_medicine/guide/med\\_qa/q33.html](https://www.jpma.or.jp/about_medicine/guide/med_qa/q33.html)

# Accelerating Trend Toward Digitalization of Drug Discovery Around the World

## Trend Toward Digitization in Drug Discovery

Drug discovery is an area in which many tasks remain non-digitalized, including manual laboratory work and record keeping that depends on individual skills. Many players in the industry actively pursue the use of digital technology in drug discovery which is anticipated to drive the evolution of drug discovery process and the discovery of innovative new drugs. With the advancements in technology such as artificial intelligence (AI), device control, Internet of Things (IoT), and sensing technology, drug discovery has the potential to achieve significant progress through digital transformation. The digitalization of drug discovery will not only improve the efficiency of drug discovery but will also allow researchers to focus more on advanced intellectual activities such as generating ideas and building hypotheses.

On the other hand, simply adopting the latest technologies without integrating them into current manual work and centralization of data might not produce the desired effects. NTT DATA believes that effective use of the latest technologies is made possible not only by adopting individual technologies but also by ensuring the digitalization and integration of the entire drug discovery process, which will then allow us to pursue drug discovery at levels of accuracy and speed that were previously unachievable.



In achieving such digital transformation, startup companies with advanced digital technologies have been attracting attention in recent years. In the U.S., investments in digital health startups have been on the rise, reaching \$14.1 billion in 2020.<sup>\*1</sup> It is difficult for a pharmaceutical company to pursue digitalization of the drug discovery process on its own, so partnering with these startups with advanced digital technologies can prove effective.

In the following sections, we present three examples of startups that are pioneering the digitalization of drug discovery.

<sup>\*1</sup> Source: Jasmine DeSilva, Megan Zweig "2020 Market Insights Report: Chasing a new equilibrium", RockHealth <https://rockhealth.com/insights/2020-market-insights-report-chasing-a-new-equilibrium/>

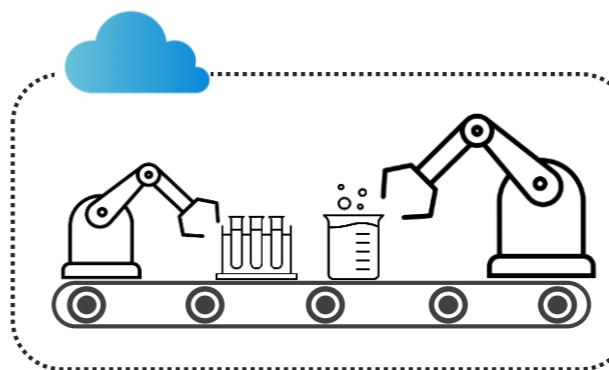
## Strateos Launch Cloud Labs: SmartLab Platform

The trend toward digitalization in drug discovery is already growing worldwide. Both emerging and big pharma companies go beyond simply improving limited aspects of operation in drug discovery to redesign their entire process through digitalization and automation. Strateos is a U.S. biotechnology company pioneering the development of remote access laboratories and lab control software using robot automation.

Strateos' SmartLab Platform is a progressive attempt to provide researchers around the world with high-quality automated laboratory environments on a cloud-based platform.

This platform leverages the Strateos resources of two SmartLab Studios, one in Menlo Park and the other in San Diego, California. The studios are equipped with robotic arms having sophisticated programming that performs repetitive experimental procedures accurately and with high precision. These Studios offer researchers around the world remote access to state-of-the-art research equipment, allowing them to drastically reduce the time required for performing experiments by an average of approximately 90%<sup>\*1</sup> and to focus on more creative activities such as hypothesis-building and data analysis and interpretation.

These are only part of the values offered by Strateos' remote-access labs. Traditionally, experiments in drug discovery have relied heavily on the skills and intuition of individual researchers, which always involves the risk of data contamination due to human error or bias. Robot automation of experiments however can minimize such errors attributed to experimenters and provide highly reliable and reproducible data.



## Robotic Cloud Lab Launched in Partnership with Eli Lilly

In addition to offering laboratory automation services on its cloud platform, Strateos also helps clients build their own remote-controlled laboratories. Most recently, Eli Lilly partnered with Strateos in 2020 to launch a robotic cloud lab, the Lilly Life Sciences Studio (L2S2) lab, as part of DX of the drug discovery process.

Being able to control the entire drug discovery process (compound design, synthesis, purification, analysis, sample management) remotely, means researchers now have access to highly reproducible, high-quality data in real time. This has drastically reduced the time required for the synthesis-to-evaluation cycle that ordinarily took several weeks to a month; down to a period now ranging from just two hours to a few days!<sup>\*2</sup>

## Transforming the Drug Discovery Scene with Cloud Labs

Strateos' cloud labs are expected to not only bring changes to individual companies/organizations but also medium to long-term transformations of the entire drug discovery scene.

One such transformation is freedom from restraints on lab equipment resources. Cloud labs will not only provide just pharmaceutical companies but also academia and drug discovery ventures with access to a rich source of lab equipment whenever and in the quantity needed, allowing them to pursue diverse drug research without being constrained by resources.

Another transformation is that they encourage innovation globally. Traditionally, access to lab results has been limited to those within the laboratories of individual R&D organizations, now however, these can be made accessible across space and time, encouraging active collaboration among researchers from different countries, organizations, and fields without borders.

<sup>\*1</sup> Source: Suchi Rudra "Strateos Is Streamlining R&D With Robots Running Cloud-Based Labs", TRUiC <https://startupsavant.com/news/strateos>

<sup>\*2</sup> Source: Eli Lilly and Company "Lilly Life Sciences Studio Accelerates Drug Discovery Process" <https://youtu.be/fX1wssRFwaE>

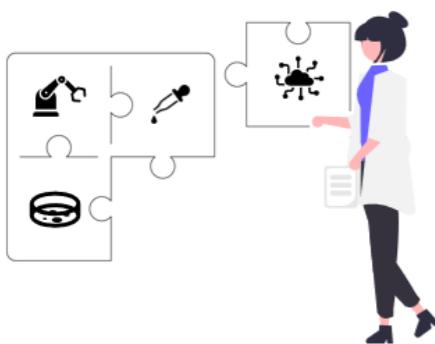
## HighRes Biosolutions Pursue Coexistence of Lab Automation and Researchers

HighRes Biosolutions is a company that offers services in building automated research processes in life science. The laboratory equipment developed by HighRes Biosolutions can be installed in laboratories and can learn to integrate, relocate, and link devices quickly and flexibly, allowing research automation and researchers to work well together. The difference from Strateos is that HighRes Biosolutions develops services to enable collaboration between existing laboratories and researchers with automated laboratories rather than simply offering lab automation.

## Scalable and Flexible Processes Achieved by Nucleus Hardware and Cellario Software

Nucleus is a modular laboratory instrument with the individual components of laboratory equipment separated by a function into blocks that can be assembled/disassembled. Individual modular devices can be easily moved on wheels and connected by joints and couplings. This allows easy installation in a laboratory and flexible modifications according to the purpose. It also allows researchers to guide the robotic arm to easily teach movements or combine multiple devices to build a sizeable multi-robot environment, allowing researchers to flexibly modify their laboratory equipment as needed to suit the changing workflow.

The individual modular devices are also equipped with Cellario software, which allows researchers to manage the automated experiments and lab materials and check the results of experiments from their own computers. The goal is to integrate and manage all devices and software in a laboratory within the laboratory.



## High Throughput Screening in Partnership with AstraZeneca

A prime example of HighRes Biosolutions' lab automation using modular devices can be seen in its partnership with AstraZeneca. To achieve the goal of automating screening assays and compound management, AstraZeneca has installed the HighRes Biosolutions' laboratory module in its R&D center, achieving high throughput screening (HTS) of a cumulative 300,000 compounds per day. This HTS system is half the size of the previous instrument and can be run up to three times faster. The entire group of assembled robots is now capable of testing 40 million compounds for 40 to 50 diseases.\*1

## Benefits of Lab Automation Using Modular Devices

R&D in the biotechnology field involves manual procedures, which are associated with challenges such as low reproducibility and efficiency and the high risk of laboratory accidents. Data show that a small number of experimental techniques are performed repeatedly in the majority of studies published in life science,\*2 and thus, automation of routine procedures is expected to improve experimental efficiency significantly. Examples of introducing laboratory robots can also be seen among Japanese companies such as Astellas' Maholo, although the number is still limited.

This issue can be overcome by a new type of experimental device that modularizes laboratory equipment to be easily moved, connected, and disassembled. Such a flexible laboratory environment will allow constant updating to the latest technology in response to rapidly changing needs in drug discovery. Modularizing laboratory equipment may soon become one of the most important concepts in drug discovery.

\*1 Source: Angus Liu "Charles River to accelerate hit discovery with AstraZeneca high-throughput deal", FierceBiotech <https://www.fiercebiontech.com/cro/charles-river-to-accelerate-hit-discovery-astrazeneca-high-throughput-deal>

\*2 Source: Ministry of Economy, Trade and Industry. Recent Policies Relating to Bioindustry [https://www.jba.or.jp/web\\_file/d2a40ffe2d4a670c08537eb06c469564b0311165.pdf](https://www.jba.or.jp/web_file/d2a40ffe2d4a670c08537eb06c469564b0311165.pdf)

## Moderna's Ultrafast Vaccine Development

The last example focuses on just a single startup. Moderna has achieved significant results through digitalization in developing a vaccine for COVID-19. Since it was first established in 2010, the company has continued to refine its mRNA technology and has successfully developed the COVID-19 vaccine alongside big pharma companies such as Pfizer by focusing on building R&D processes and manufacturing and distribution systems through DX. The keys to Moderna's groundbreaking drug discovery R&D are *mRNA* and *DX*.

### mRNA Platform Strategy

The company was one of the first to focus on mRNA and has been working to develop all types of drugs and vaccines using mRNA. Adopting mRNA allows the teams to apply their own knowledge and technology to the development of several types of drugs. Furthermore, the same drug manufacturing technique can be applied to a range of disease types thus facilitating digitalization. This allows for shorter development times, lower development costs, and a wider scope of prophylaxis and therapy. This constitutes Moderna's *mRNA platform strategy*.<sup>\*1</sup>

The mRNA-based approach to development is expanding beyond COVID-19 vaccines, and the market is expected to grow to \$23 billion by 2028 to 2035.<sup>\*2</sup>

## Digitalization Strategy

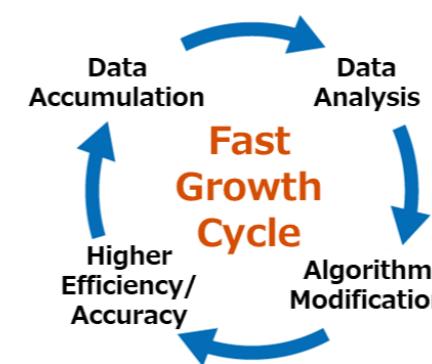
To establish the mRNA platform, Moderna focuses on investing in state-of-the-art infrastructure as its unique digitalization strategy. To digitalize the entire operation, the company has migrated all of its internal data to a cloud-based platform for integration. Moderna has also introduced automation and robotics to make a shift to a production system that does not involve human intervention, which allows them to run many experiments and tests, enabling data accumulation and accurate analysis. Based on such infrastructure, Moderna runs an operation cycle that modifies and improves the accuracy of algorithms and research techniques at high speed, thereby pursuing the mRNA platform strategy.

### mRNA and Digitalization

Despite being a young company founded only in 2010, Moderna has pursued its unique strategy for drug discovery R&D and has grown to become known around the world for the development of the COVID-19 vaccine. Behind this growth lies a mechanism that is built like a technology company despite being a pharmaceutical company. Its approach to development which combines *mRNA* and *DX* can serve as a model for using technology to solve challenges in drug discovery such as shortening development times, cutting costs, and searching for the right targets.

\*1 Michiaki Tanaka. *Why was Moderna Able to Make a Vaccine in Three Days?* Shueisha International.

\*2 Source: Wen Xie, Baiping Chen & John Wong "Evolution of the market for mRNA technology" <https://www.nature.com/articles/d41573-021-00147-y>



# Digitalization of Drug Discovery Improves Patient Experience of Patient-Centered Care

## Patient-Centered Medical Experience and the Digitalization of Drug Discovery

NTT DATA believes that an important role for players involved in the future of the healthcare industry will be to *transform the patient-centered Medical Experience through healthcare DX* (MX), which we promote as the **transformation of MX**.

The transformation of the drug discovery process through digitalization as seen in the three aforementioned examples will significantly improve the efficiency of drug discovery.

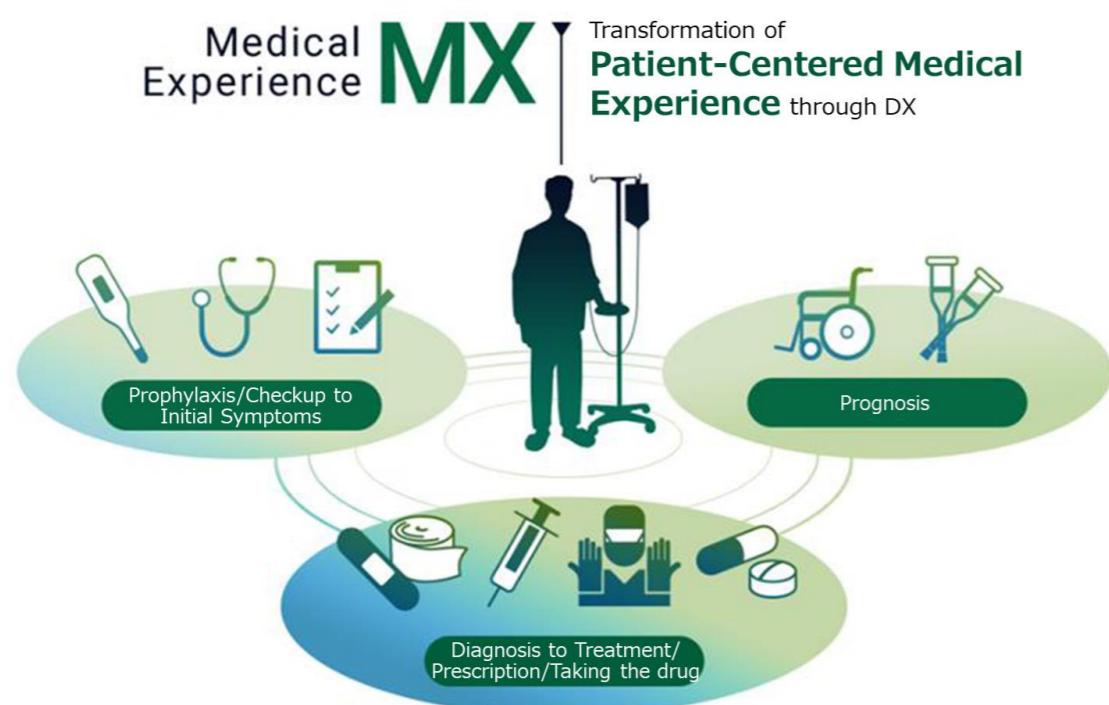
Automating the entire research process will allow for faster and more accurate experiments and operational processes as well as reduce the time required for investigational and routine tasks, thereby reducing research costs and development time. In addition, the accumulation of experimental data and know-how and the integration of AI tools will enable the effective use of the latest technologies, achieving levels of accuracy not previously possible. Further, the automation and remote-controlling of laboratory equipment and the recording and storing of all real-world activities in digital space will accelerate the drug discovery cycle and establish a mechanism that allows for continuous improvement of operational and laboratory processes through a data-driven PDCA

cycle. This will achieve the discovery of groundbreaking new drugs with higher accuracy and speed.

Digitalized drug discovery will not only streamline the drug discovery process but also drastically improve the patient experience of patient-centered care. For example, reductions in research costs will allow teams to pursue drug discovery for refractory diseases that were previously unprofitable. It also allows researchers to focus on activities such as hypothesis-building and new modality search, enabling the rapid development of new drugs and vaccines for new diseases and the development of drugs with fewer side effects to meet the needs of individual patients.

Furthermore, digitalization will allow for the use of healthcare data from individual patients, which enables us as a pharmaceutical company to provide more personalized support to individual patients. Using genetic and epidemiological information to obtain a more segmentized view of conventional diseases will lead to more personalized drug discovery.

As shown here, the digitalization of drug discovery is at the core of MX transformation. It not only streamlines research to achieve the discovery of groundbreaking new drugs but also directly impacts the patient experience of healthcare.



# Chapter 2

NTT DATA's Vision for the Future of Drug Discovery



## New Approach to Drug Discovery Research Through Accelerated Drug Discovery Cycle

### NTT DATA's Vision of Future Drug Discovery Processes

As the environment surrounding the drug discovery business becomes increasingly challenging, the transformation of drug discovery processes through digitalization has become more important than ever. NTT DATA believes that the future of drug discovery processes, transformed by digitalization lies in the **acceleration of the drug discovery cycle**.

Acceleration of the drug discovery cycle refers to the significant reduction in the time required for one cycle of the drug discovery process and the establishment of a drug discovery cycle that is automatically improved in speed and accuracy. We believe that in addition to simply accelerating the process, we will be able to achieve an autonomous system that continuously improves operational and experimental processes through a data-driven PDCA cycle.

Further, digitization will drastically shorten the time required for investigational and routine tasks, which used to take an enormous amount of time. This means that researchers can focus on more creative and artistic work such as building hypotheses, exploring new modalities, and collaborating with researchers around the world.

The key to such transformation will be the automation and remote-controlling of laboratory equipment, and the digital twinning of all real-world activities by recording and storing them in digital space.



Automation and remote-controlling of laboratory equipment will drastically accelerate the drug discovery cycle by enabling the continuous operation of laboratory equipment and the sharing of laboratory equipment resources on a global scale. It will also free researchers from the burden of performing enormous amounts of experimental procedures, and allow them to focus on highly intellectual activities.

Digital twinning involves the aggregation and visualization of all data in the drug discovery process, from experimental data and researchers' thoughts and actions, to clinical research data. The accumulated big data enables highly accurate AI simulations and hypothesis building, as well as comprehensive and quantitative review and improvement of the entire drug discovery process. This will allow the drug discovery cycle to grow by repeating the planning, execution, and improvement in an accelerated and autonomous manner.

In future drug discovery, the researchers will be able to discover groundbreaking new drugs at an unprecedented speed through digital transformation.

#### Advances in laboratory equipment and improvement in sensing performance

- Full automation of cell culture and synthesis experiments
- Automated data entry from lab equipment into electronic lab notebooks

#### Tracking of skilled scientists and digital twinning

- Improvement in speed and reproducibility of experiments through extraction, verbalization, and learning of *tricks* and experimental know-how and techniques that cannot be expressed in language
- Highly accurate hypothesis building and efficient investigation by learning the processes of hypothesis building, human thought process experiments, and investigational activities

#### Output derived from high-quality big data, unparalleled computational complexity, and superior algorithms

- Drug discovery targets derived from clinical information with omics data and deep learning
- Rapid candidate synthesis through ultra high-accuracy virtual screening

#### Experiments beyond physical boundary constraints

- Encourage collaboration with overseas laboratories through advanced VR technology and remote-controlled experiments
- Experiments are performed by robots 24/7

# Changes in Operation Facilitated by the Digitalization of Drug Discovery

## Overview of More Digitalized Drug Discovery Operation

How will the digitization of the drug discovery process change the performance of drug discovery tasks?

Digitally recording all of the various findings and data obtained in drug discovery will allow us to make highly accurate simulations by AI and provide consistent and quick predictions throughout the target search, compound screening, and pharmacological activity/safety steps. Based on these predictions, AI and researchers can collaborate and mutually assist each other to repeat the process of hypothesis building and testing at high speed, thereby improving the success rate of drug discovery.

This is followed by AI determining the optimal experimental design and parameters according to the disease and compound and automatically running laboratory equipment that performs drug discovery activities without human intervention.

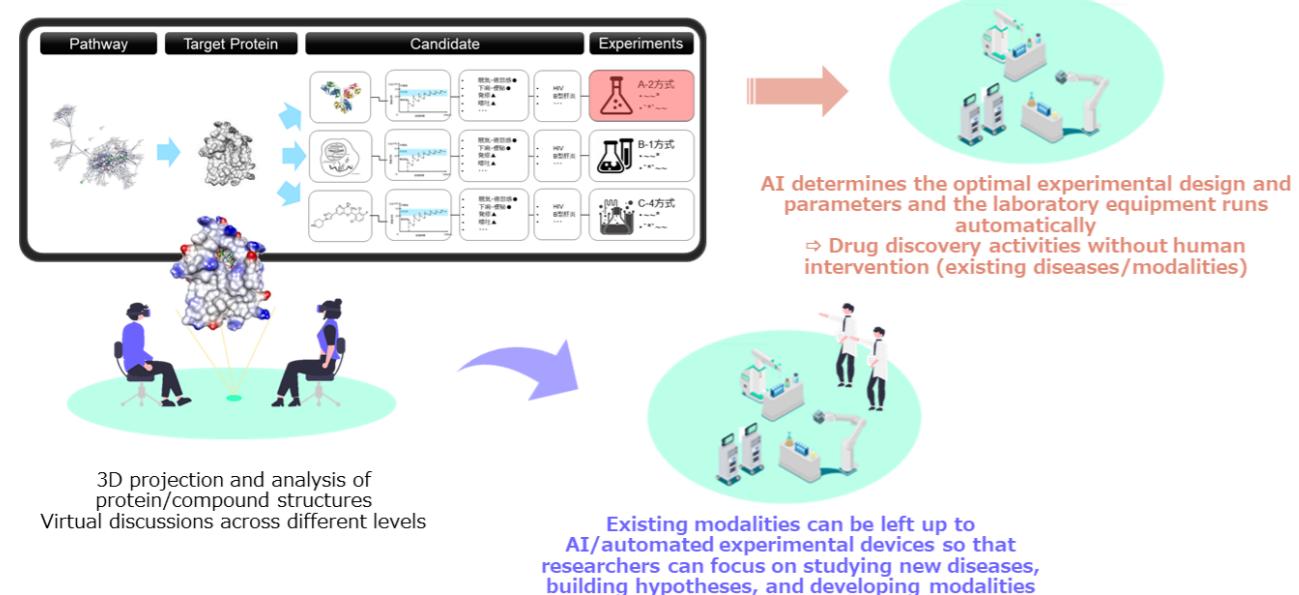
Diseases whose mechanisms are well understood

and existing modalities can be left to AI/automated lab equipment, so that researchers can themselves focus on studying new diseases, building hypotheses, and developing modalities.

Digitalization and integration of the entire drug discovery process will enable drug discovery activities to be performed at a level of accuracy and speed that was previously unattainable. Not only will it automate and improve the accuracy of individual tasks, but also seamlessly link the individual drug discovery processes, allowing for hypothesis building/testing and the improvement of experimental reproducibility and prediction of results across chemical and biological processes.

On the next page, we divide the drug discovery activities into three phases, namely, *target identification/validation*, *compound screening*, and *drug discovery chemistry & pharmacodynamics/pharmacokinetics*, in order to specifically discuss how the operational processes will change. Here, we use low molecular drugs as an example.

Highly accurate and consistent simulations throughout target search, compound candidates, and pharmacological activity/safety  
⇒ Improved drug discovery research success rate through collaboration and mutual assistance between AI and researchers



## Target Identification/Validation

This is the first phase in drug discovery and involves determining the cause of the disease, determining the pathogenic mechanism, identifying the target molecule, and validating the target.

Researchers examine external information such as published papers and patents, as well as internal data to analyze disease mechanisms and search for drug discovery targets. However, external information comes in vast quantities and varies in format, and the internal data are not fully integrated, thereby likely constituting challenges for many pharmaceutical companies. Digitalization of drug discovery will enable automatic and comprehensive examination and searching through a vast amount of data, allowing researchers to search for compound candidates in a shorter period of time based on a broader range of information than is possible by making manual examinations and searches.

## Compound Screening

In this phase, after candidate compounds are identified, researchers will develop assays, perform screening, and design experiments. We can see that the use of IT in individual areas such as screening and compound simulation is constantly expanding. At the same time, we believe that one of its challenges is the lack of smooth coordination and information transfer among these systems.

These systems will be integrated onto a single data platform to seamlessly execute the processes throughout candidate compound search and screening and compound simulation. Screening accuracy is improved by repeating assay development. The AI can then use the results from that exhaustive information search to automatically design truly necessary experiments.

## Drug Discovery Chemistry and Pharmacodynamics/Pharmacokinetics

The drug discovery chemistry phase involves the designing and synthesizing of compounds based on the experimental design and optimization of hit compounds. This may be an area where AI has been used more successfully than in the target identification phase although challenges still remain. For instance, the lack of integration of data environments and tools may have prevented the sufficient accumulation of experimental data and know-how. The experimental results are also often dependent on individuals' skills, resulting in poor reproducibility of experimental results.

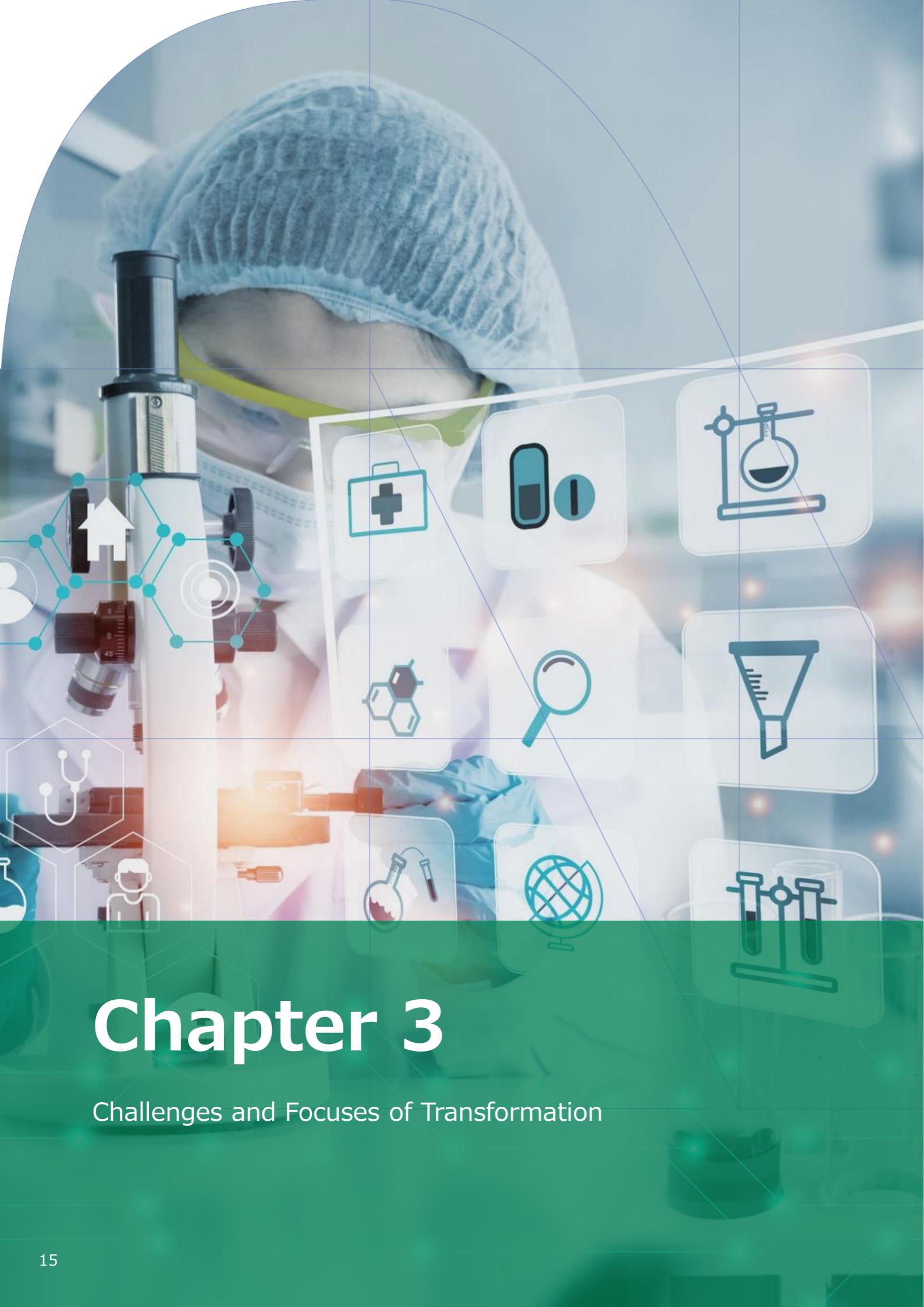
By integrating the entire laboratory into the IoT, experimental data can be digitally visualized and accumulated as data. Further, robotic automation of experiments will eliminate dependence on individual skills from experimental results and improve reproducibility.

The pharmacodynamics/pharmacokinetics phase involves pharmacodynamic/pharmacokinetic studies and preclinical studies to confirm the pharmacokinetics and safety. One of the challenges here may be that it is difficult to predict the uncertainty involved in successful drug development and its safety.

Digitalization of drug discovery activities will enable the use of AI to predict the results during the experiment and to perform more sophisticated efficacy and toxicity simulations thereby shortening the experimental period and reducing the number of animal experiments.

# Chapter 3

## Challenges and Focuses of Transformation



# Current Challenges in Drug Discovery and Focus Points of Transformation

## Summary of Challenges in Drug Discovery Processes

To understand the current challenges faced in drug discovery, we examined the policies of pharmaceutical companies, conducted interviews with experts, and investigated the findings from NTT DATA's case studies. We mapped the challenges identified during our investigations on a chart with two axes. We set one axis as the overall drug discovery process and the other axis as the flow of individual research operations in order to visually organize their positioning. We then grouped the challenges into those *common* to all processes (blue box in the figure below) and those *specific* to particular processes (purple box in the figure below).

Process-specific challenges may include:

- Target identification/validation: poor quality of data required for hypothesis building and testing, difficulty in accessing data
- Compound screening: lack of compound libraries for new drug discovery targets, difficulty in learning biotechnological drug discovery techniques

- Drug discovery chemistry: challenges in improving the accuracy of docking simulations
- Pharmacodynamics/pharmacokinetics: toxicity testing requires a great amount of time and money, and the current trend is to avoid animal testing for ethical reasons.

Drug discovery technologies are undergoing rapid advancements beyond the boundaries of life sciences, which makes these technologies a major challenge for pharmaceutical companies to adapt.

Challenges common to all processes may include:

- Researchers spend a lot of time on investigational work that involves searching through enormous amounts of information, designing experiments, and routine tasks
- Lack of human resources capable of performing data analysis, lack of analytical equipment resources
- Difficulty in sharing research know-how.

The difficulty underlying these issues may be in balancing day-to-day research operations with efforts to create new values.

		Drug Discovery			
		Target Identification/Validation	Compound Screening	Drug Discovery Chemistry	Pharmacodynamics/Pharmacokinetics
Research Flow	Hypothesis building	Too many media need to be searched causing poor understanding of unmet medical needs & poor evaluation of drug discovery concepts			
	Examine validation methods	Limited access to data sources needed for target identification			
	Determine validation methods	Poor quality of data from secondary databases such as public databases, making it difficult to search for meaningful information			
	Draw up validation procedures				
	Draw up a timeline				
	Perform experiments		Difficulty in identifying the best modality from multiple modality candidates		
	Obtain data		Lack of compound libraries directed at finding new targets		
	Statistics				Trend is toward avoiding animal testing for ethical reasons
	Interpretation				The current process (system) requires a great deal of time and money for toxicity testing
Common		<ul style="list-style-type: none"><li>• External information such as published papers, patent data, and RWD and internal information such as lab notes/reports are not managed in an integrated manner which makes research complicated</li><li>• Research accuracy and time vary according to the individual researcher</li><li>• Researchers draw up experimental designs based on search results and by referring to past information. They need to carefully examine large amounts of information and devise an optimal experimental design</li><li>• Researchers are too busy with routine work to devote time to high value -added work that requires creativity</li><li>• The specifications of DB and analytical equipment are not sufficient for performing large -scale calculations</li><li>• Lack of specialized personnel skilled in statistical analysis</li><li>• Lack of sharing of know-how among researchers (success factors, techniques, research notes/records, progress)</li></ul>			

# Four Focus Points in Transformation Towards Digitalization of Drug Discovery

## Areas of Digitalization Efforts and Changes in Operation

Based on the elements shared by both challenges common to all processes and challenges specific to particular processes, we have identified the following three major areas of digitalization efforts in drug discovery.

- Area 1: Discovery/design (before experiments)**

**Establishing a high-quality and high-speed** environment enabling the examination of internal information (lab notes/reports, etc.) and external information (published papers, patent data, RWD, etc.) and the **development of optimal experimental designs** based on examination results, in the discovery phase before performing experiments.

- Area 2: Experimental process**

Digitalizing experiments using robots and IoT devices, and **establishing an experimental environment in physical and digital spaces that allow for continuous improvement in reproducibility at high speed**.

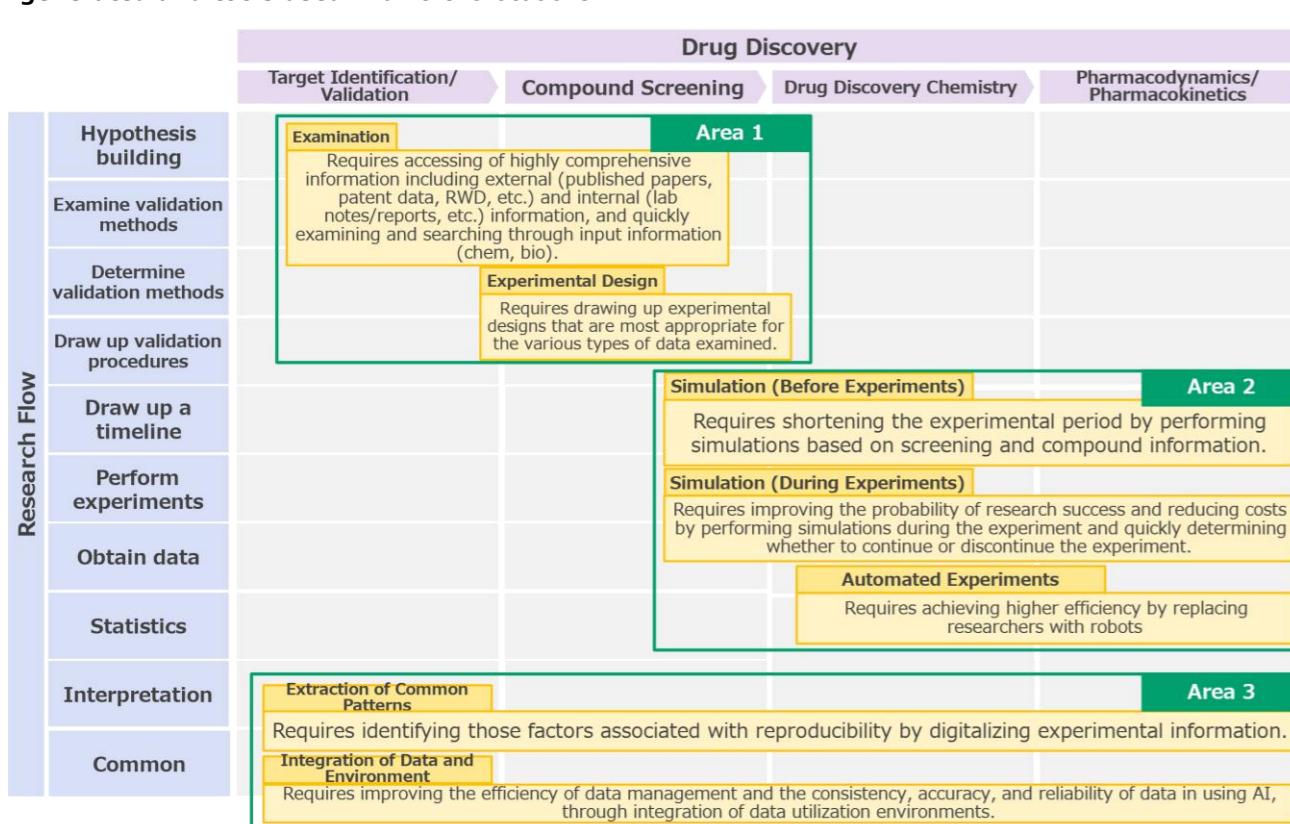
- Area 3: Use of IT**

**Establishing an environment where all data generated and tools used** in different locations

and processes within the company are **consolidated onto a single data platform to allow data utilization**.

Consolidating all input, process, and output data from throughout the drug discovery process onto a digital platform, with a focus on these three areas, will allow us to build a **coherent, digitalized laboratory**. Doing this is expected to significantly improve efficiency and accelerate the drug discovery process. This will also lead to digital twinning in the future. As discussed in Chapter 1, Moderna and Strateos are successful examples of pioneering transformations in experimental design, simulation, and automated experimentation.

As this transformation progresses, operations in drug discovery will likely undergo drastic changes. Advancements in tools and AI and the integration of data and know-how will allow chemists and biologists to understand and share their findings and operations with each other more easily. This will also free researchers to perform some of the tasks in other work areas or develop drug discovery ideas based on broad knowledge.



## Four Transformation Focus Points in the Areas of Digitalization Efforts

Solving the challenges in all the processes of drug discovery will greatly contribute to achieving our vision for future drug discovery. NTT DATA aspires to establish an ultrafast drug discovery cycle through the following four focus points in transformation in the areas of digitalization.

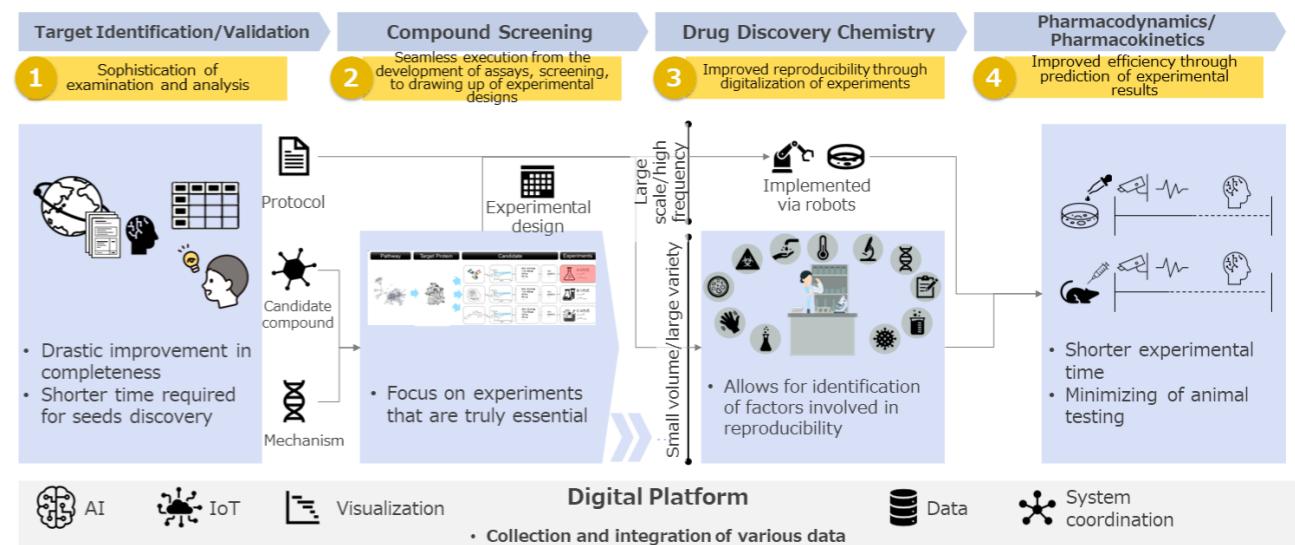
- 1. Sophistication of examination and analysis**
- 2. Seamless execution from the development of assays to the drawing up of experimental designs**
- 3. Improvement in reproducibility through the digitalization of experiments**
- 4. Improvement in efficiency through prediction of experimental results**

In Focus 1 above, examination sophistication and analysis tasks by applying AI will allow us to obtain more promising information from a much larger amount of data and in a shorter time than is possible by manual work. In Focus 2, establishing a seamless flow of processes up to experimental designing will allow us to focus only on truly essential experiments and move on to other experiments in a shorter period of time.

In Focus 3 and 4, the entire laboratory will be IoT-enabled to identify factors that will allow us to eliminate failures that are dependent on humans and environments. Further, automating experiments will improve reproducibility and the success rate. Predicting the results from experiments using information collected by IoT-enabling of the entire laboratory will also shorten the time required for experiments.

We believe that by pursuing these focus points of transformation, we can digitalize and integrate the entire drug discovery process, allowing for drug discovery activities to be performed with an accuracy and speed that was impossible up to now.

The four focus points of transformation are discussed in detail on the following pages.



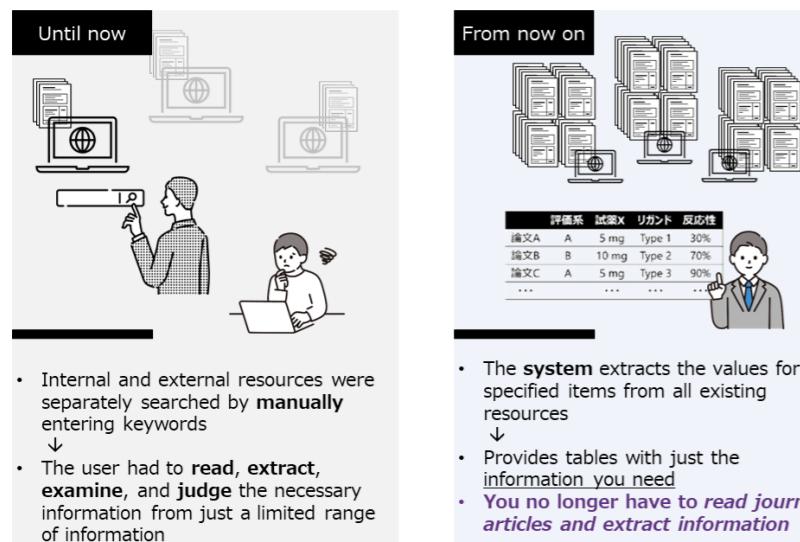
## Focus of Transformation 1: Sophistication of Examination and Analysis

Up until now, in examination and analysis tasks associated with drug discovery target identification and validation, we had to search separate resources such as academic databases and internal documents by entering keywords one by one to search for necessary information. However, manual information searching requires an enormous amount of time and often does not yield the desired information.

The *heavy burden on researchers* and the *lack of completeness* inherent in manual examination and analysis are challenges to be solved as the first step toward pursuing a high-accuracy and fast drug discovery process.

In solving these challenges, an advanced examination and analysis system would prove effective, which will automatically search through and extract items from a wide range of information not practical for a single person to read, and present suggestions and hypotheses derived from such information.

Such a system will consolidate and process all types of internal and external data such as academic papers, patent information, external databases, environmental information, experimental data, and internal reports in an integrated manner and automatically search for and extract information on a specified target. It is capable of searching through a wide range and vast volume of information at high speed that could never be read by a single person and in a comprehensive manner, which will help to reduce the human workload and allow making examinations with high accuracy.



The system will not merely search and extract information, but can also use natural language processing AI to automatically structure and chart the extracted information, presenting suggestions and hypotheses that we truly need.

By analyzing and graphing conditions that affect experimental results from a large amount of published data, providing a list of promising candidate compounds along with the reasons for selection, presenting hypotheses about the mechanisms of target diseases, and by deriving efficient experimental protocols based on numerous examples, the useful information provided by AI is fully expected to drastically improve both the quality and speed of human judgment.

The sophistication or upgrading of the examination and analysis process by such a system is expected to:

- Drastically improve the completeness of information search
- Reduce the time required for seeds discovery.

This will lead to improved accuracy and acceleration of the drug discovery process. It will allow researchers, who have traditionally devoted much of their time and effort to examination and analysis in the target identification/validation phase, to engage in more creative work, which will serve as a solid driving force for generating breakthrough new drugs in the current industry environment where drug discovery is becoming increasingly challenging.

## Focus of Transformation 2: Seamless Execution From the Development of Assays to Drawing Up of Experimental Designs

Experimental designs are drawn up a number of times in drug discovery during various processes such as drug discovery chemistry, pharmacodynamics/pharmacokinetics, and safety, which requires that the details of compounds being synthesized, the expected timing of synthesis completion, and the method of testing be coordinated across processes and departments. Communication is required frequently among many departments, which can cause miscommunication in some cases. Automating the coordination and communication among departments will allow for the smooth execution of processes from screening, assay development and experimental designing. Seamless coordination between processes enables centralized management of the drug discovery process and real-time visualization of the entire process.

Further, this seamless coordination not only improves overall efficiency, but it also improves the accuracy and speed of individual phases, by utilizing integrated, accumulated data and providing feedback to the preceding process based on the results of the subsequent process, thus automatically optimizing the process.

### ● Assay development

Automatically reconstructing assays according to their results will improve the accuracy of individual

experiments such as by extracting and reducing suspected false negatives and false positives. Reducing the number of false negatives will lower the possibility of missing a potential compound, minimizing opportunity loss.

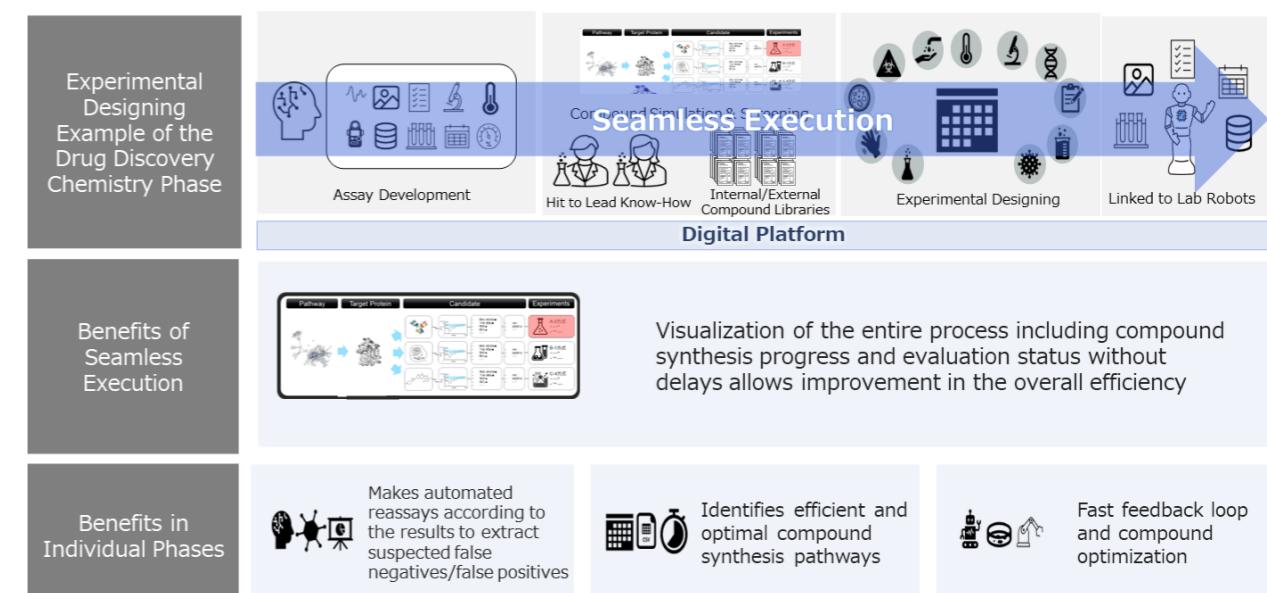
### ● Compound screening and simulation

Accumulated big data enables highly accurate AI simulations and hypothesis building. Improved coordination between systems will also allow for faster compound optimization.

### ● Experimental designing

This step compares the number of steps and synthesis costs to identify efficient and optimal compound synthesis pathways. Also, advanced AI is used to design experiments automatically, allowing for the seamless execution of the processes from assessment to experimental designing.

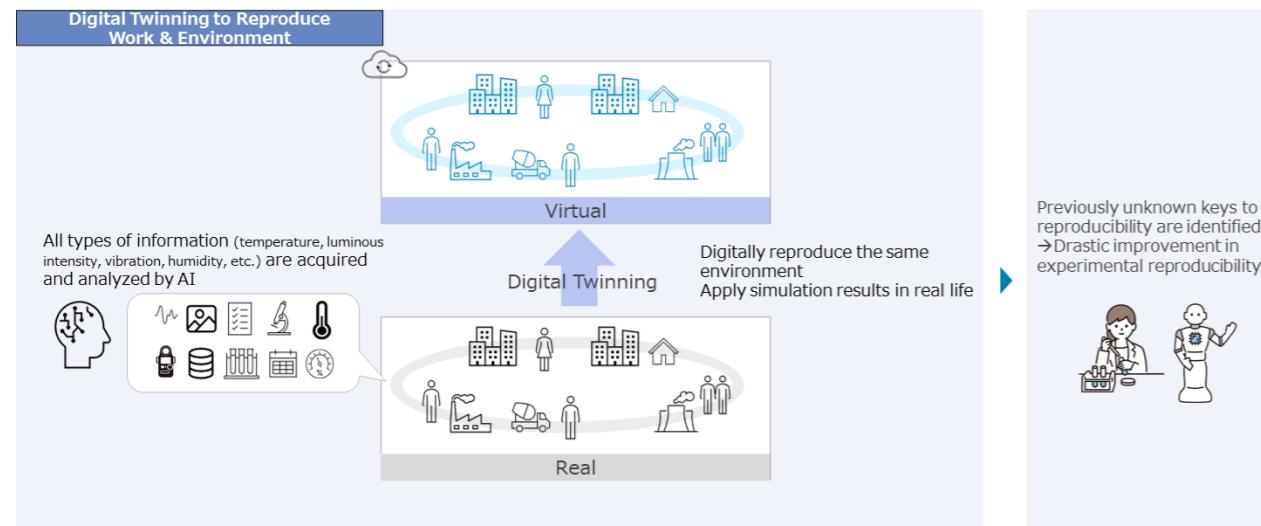
Automation and seamless execution of the processes will achieve optimization of both the overall process and the individual phases to drastically improve the accuracy and speed of compound screening. Integrating the individual systems on a single data platform will accelerate the cycle of assay development, screening, and compound simulation. Further expanding the seamless execution to include the automation of experimental designing and the subsequent running of experiments will achieve a feedback loop across processes, establishing an autonomous and continuous improvement cycle for the entire drug discovery process.



### Focus of Transformation 3: Improvement in Reproducibility Through Digitalization of Experiments

Ensuring reproducibility is essential in drug discovery experiments. Poor reproducibility in experiments may result in having to repeat experiments more frequently due to failure to obtain the desired results or to loss of reliability in the results.

There are two approaches to resolving this challenge. One is **digitalizing, analyzing, and using experimental records**. Using cameras and sensors to digitally record researchers' experimental work and environmental factors will reduce omissions and errors in work records and allow detailed analysis of factors contributing to the success or failure of experiments. Another approach is the **automation of experiments and the autonomous optimization cycle**.



Robotic automation of experimental work and autonomous optimization of the experimental process ensures stable reproduction of experimental results.

The goal of these two approaches is to virtually reproduce the drug discovery experimental processes in a digital space, in other words, digital twinning. Recording and storing all real-world experimental data and processes in a digital space allows real-time visualization and analysis as well as experimental simulations in a virtual space. Performing experiments in virtual space enables us to control various experimental conditions as parameters and run a large number of experiments without resource constraints. This lets us identify those factors limiting reproducibility and optimize experimental conditions in a fast and exhaustive manner. This in turn will also allow us to run various experiments in physical space with a high probability of success through a small number of trials by extracting optimal experimental conditions in advance from the accumulated virtual experiment data.

### 3-1 Digitalizing, Analyzing, and Using Experimental Records

Experiments in traditional drug discovery are often performed and recorded by handwritten reports and therefore have inherent challenges or issues such as the following:

- Making entry errors when recording and forgetting to record items
- Unidentified behavior such as from granularity and environmental factors influences the results.

This means that the experimental results depend on individual skills, often resulting in situations where researchers fail to obtain consistent results despite following the same procedures based on the records.

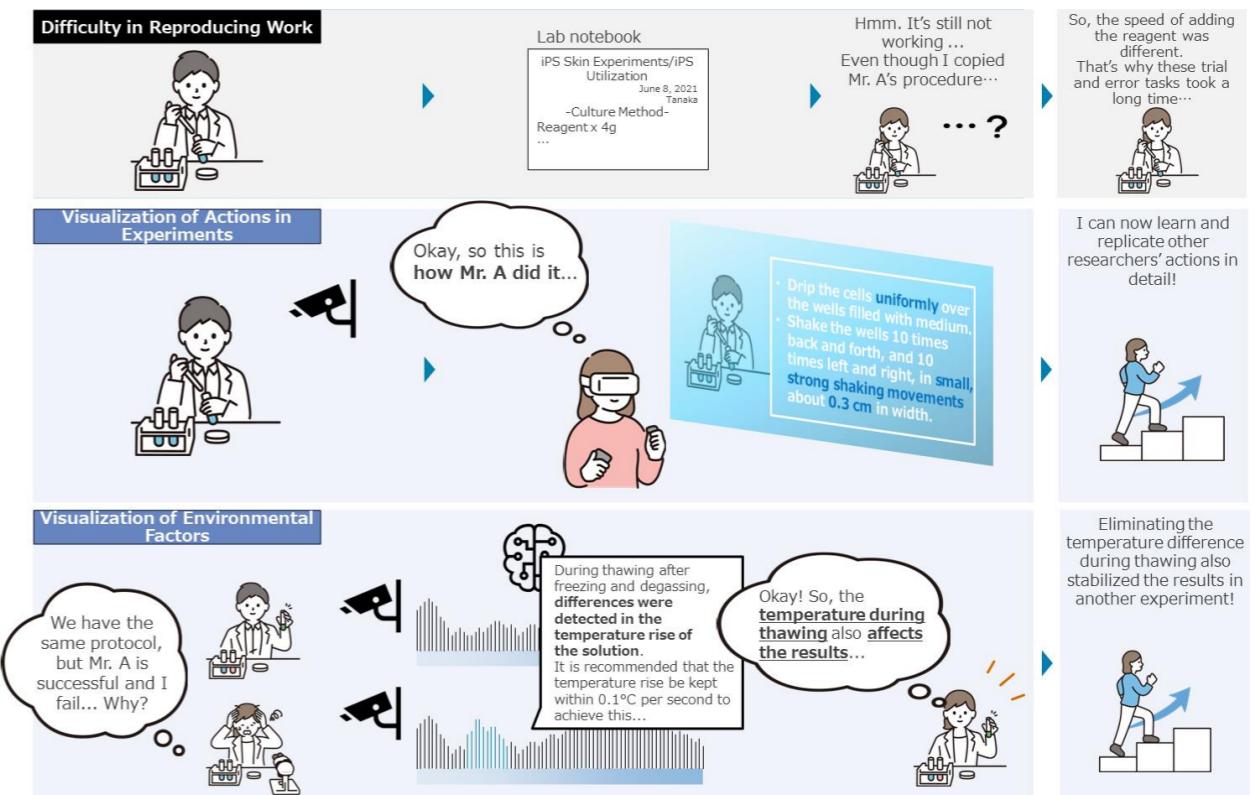
We believe that these challenges can be addressed by two approaches based on the digitalization of experimental records.

One approach is the **visualization of actions during experiments**. In this approach, procedures performed by researchers are automatically recorded and visualized utilizing cameras, motion capture, and sensor-equipped experimental equipment. This reduces the risk of recording

errors and forgetting to record items, and also enables quantitative analysis and recording of researchers' actions during an experiment. This further allows us to analyze any factors in success/failure including previously unrecognized minor actions which are likely to improve the reproducibility of experiments.

Another approach to digitalization is the **visualization of environmental factors**. Various sensors are installed in the lab to accumulate data on the experimental environment, such as temperature, humidity, air pressure, and the number of particulates in the air. By linking this laboratory environmental data with researchers' work records, laboratory environmental data during experiments can be automatically recorded. This data can then be utilized to analyze differences in lab environment data during the same experiment, which is expected to help us identify previously unrecognized environmental factors that affect the success or failure of experiments.

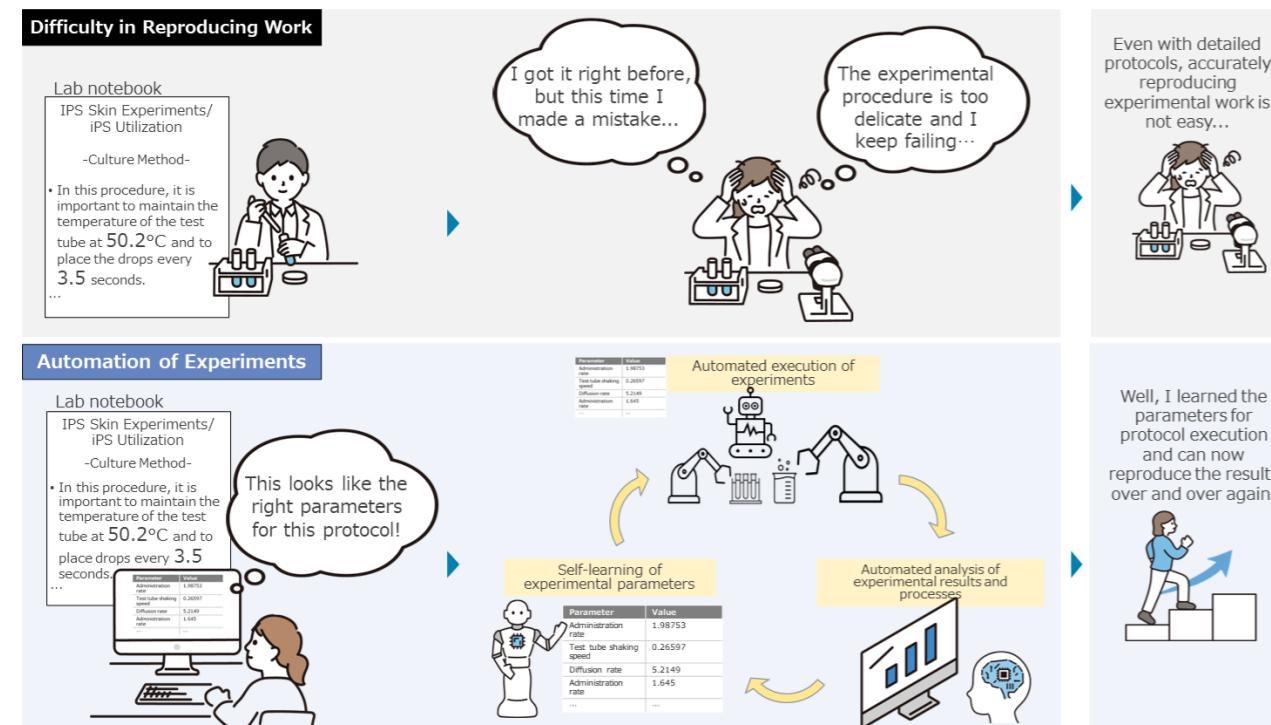
A comprehensive analysis of researchers' action data and the lab environment data will allow us to identify in detail factors in limiting reproducibility which can then be improved.



### 3-2 Automation of Experiments and Autonomous Optimization Cycle

Visualization of actions during experiments and environmental factors will help us identify those factors affecting the success/failure of experiments, and use this information to improve and define the experimental designs, thereby improving the reproducibility of experiments. On the other hand, the reproducibility of an experiment depends not only on the quality of the experimental design but also on how well the experimenter can execute the design. In experiments that involve complex processes and require delicate manipulations, just a minor difference in the researchers' actions, such as the strength used to shake the test tube and the timing and dropping speed can affect the experimental results and reduce the reproducibility of the experiment.

We therefore believe that further improvement in reproducibility can be effectively achieved by **robotic automation of experiments**. The movement of robots during experiments can be finely controlled based on parameters (quantitative variables) such as the order in which reagents are added, the stirring speed, and the dropping angle. This allows for accurately performing the actions specified in the experimental design and obtaining stable and consistent results.



Further, this approach uses the experimental design, parameters, and experimental results to analyze the factors in success/failure, based on which the parameters are modified and the experiment is repeated. This will allow the robots to **make improvements autonomously and learn the optimal parameters for the experimental process**.

The robotic automation of actions during experiments will enable stable execution of experimental procedures and autonomous, robotic process optimization which will further improve the reproducibility of experiments.

### Focus of Transformation 4: Improvement in Efficiency Through Prediction of Experimental Results

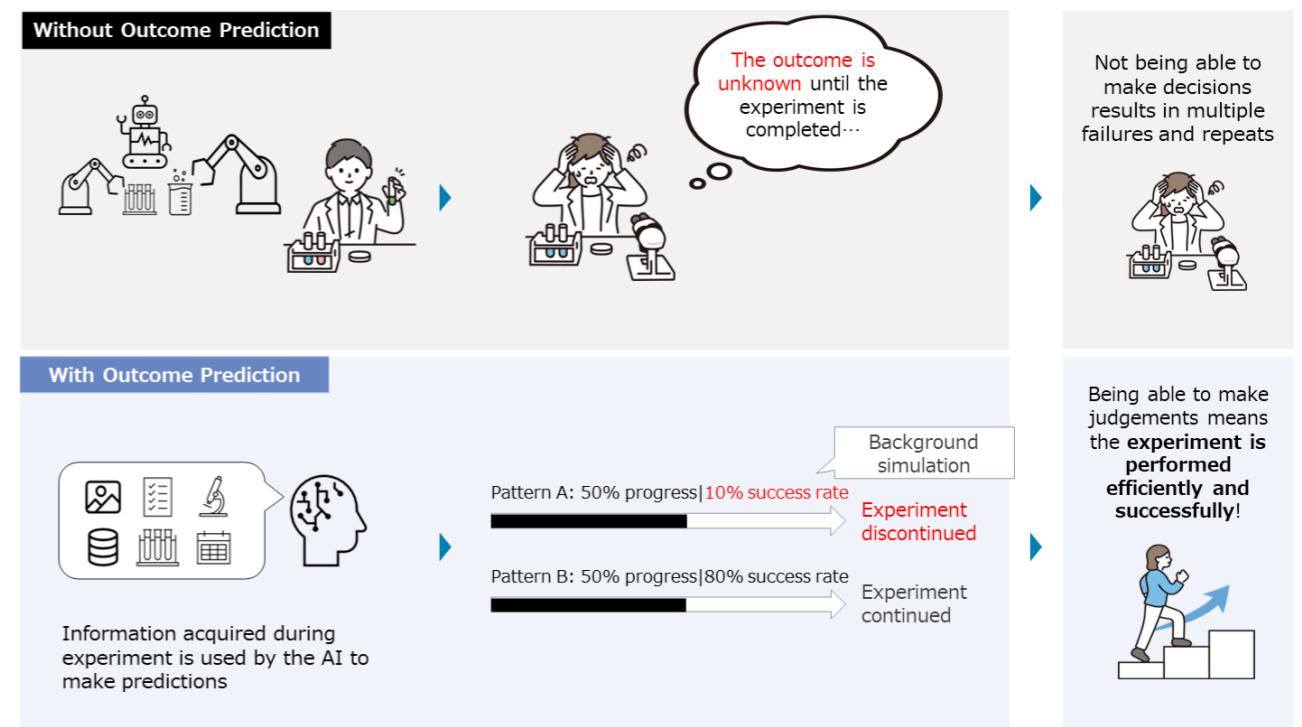
By making decisions to continue or discontinue experiments based on predicted experimental results, we can focus our resources on experiments with a high probability of success.

Experiments require numerous trial and error attempts and consume enormous amounts of time, money, and valuable materials. One of the reasons for this is that the success/failure of an experiment cannot be determined until the experiment is fully completed.

This can be solved by predicting the probability of success based on information such as the researcher's actions observed during the experiment, status of the experimental object, measurements from the experimental equipment, and laboratory environmental data. Based on this prediction, decisions on whether to continue or discontinue the experiment can be quickly made, thereby improving the probability of research and reducing costs.

To predict the experimental results, we can use the experimental data collected in the lab in Focus 3 and the AI that utilizes these data as inputs to predict experimental results. We first accumulate experimental data such as the experimental procedures, actions performed by the researcher during the experiments, lab environment data, and the status of reagents, and also have the AI learn success/failure or good/bad patterns. By inputting experimental information monitored during the experiment, the AI can predict the success probability of the experiment. We can then continue the experiment if this probability is above a certain level, or discontinue it if it is below that level, to allow the experiment's efficient performing.

Such experimental outcome prediction therefore not only saves resources but also enables a more accurate and faster experimental cycle.



# Digital Platform as the Foundation of Transformation

## Digital Platform to Support Transformation

In order to pursue the four focus points of transformation derived from the current challenges faced in drug discovery, it is essential that data from various locations and processes is stored digitally and available for use as inputs. This makes it important to develop a cross-process digital platform that consolidates internal and external data and integrates and manages software and AI used in individual processes.

A digital platform is a data platform that consolidates and processes all types of data such as experimental notes, laboratory equipment, environmental data, published data, patent information, and external databases. Various software and AI are planned to be implemented on this data platform and managed in an integrated manner to achieve more accurate and accelerated processes in drug discovery.

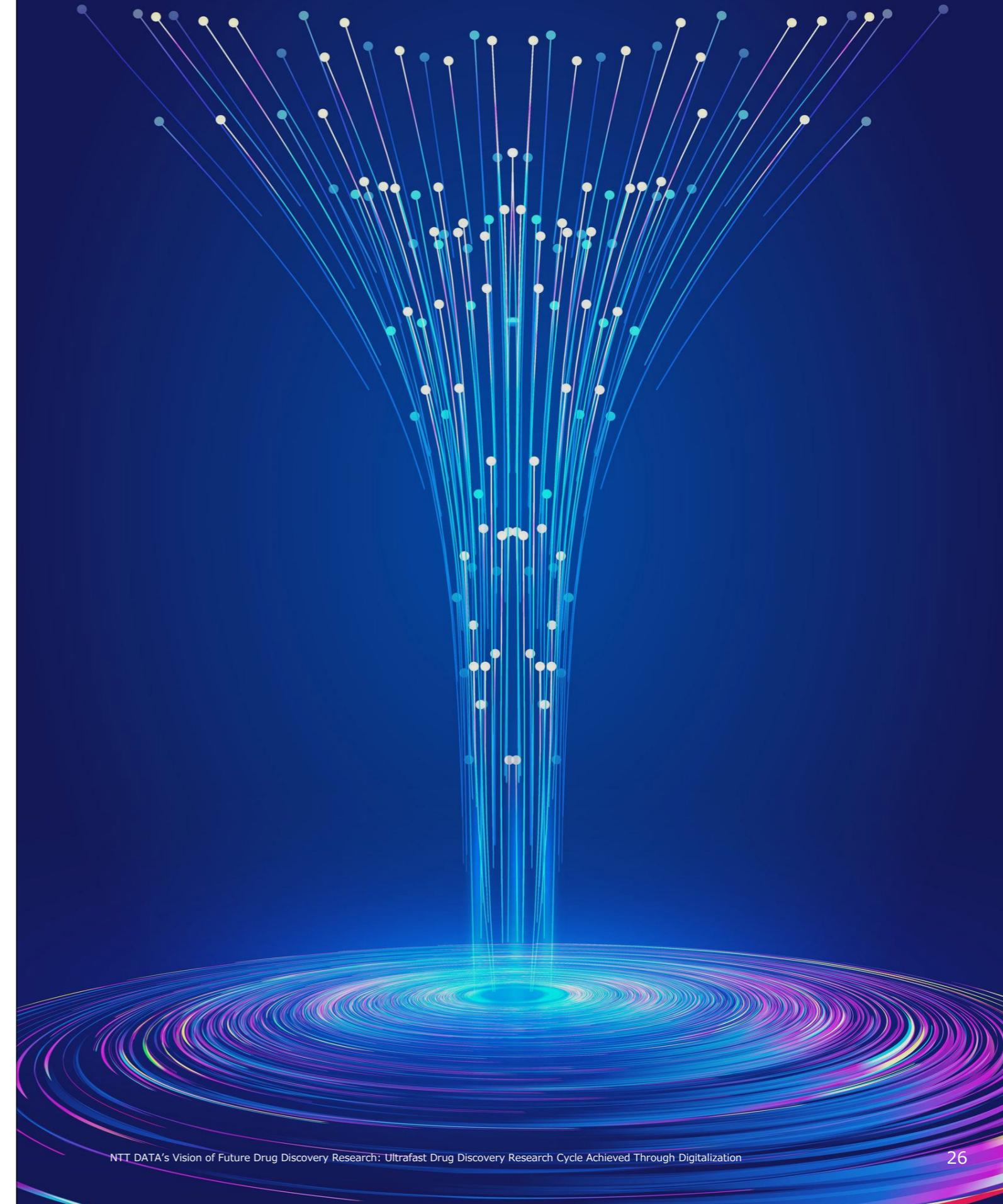
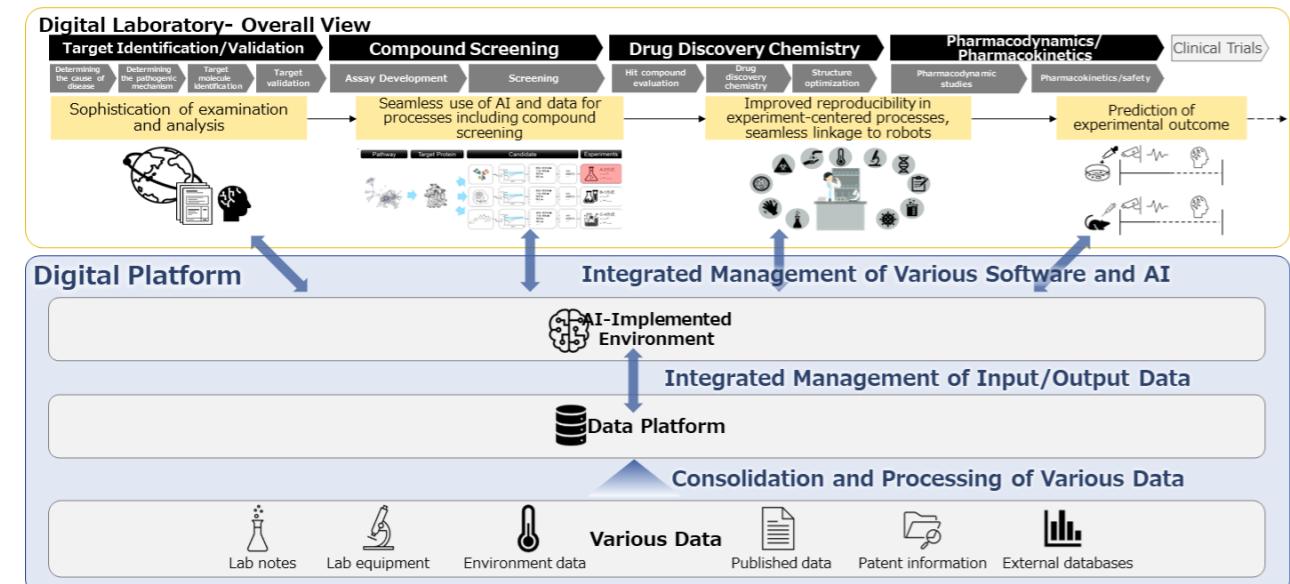
Such a digital platform will not only transform current business operations but is also closely linked to achieving NTT DATA's vision of future drug discovery.

NTT DATA's vision of future drug discovery is mainly comprised of an accelerated drug discovery cycle achieved by automation and remote-controlling of laboratory equipment and digital twinning.

AI and software running on the digital platform will not only achieve faster and more accurate execution of the individual phases of drug discovery but will also link all the phases seamlessly, thereby significantly reducing the time required for a single cycle of drug discovery. Further, any outputs generated in the drug discovery process will be repeatedly stored on the digital platform and can be used as inputs. This constitutes an autonomous improvement cycle centered on the digital platform that can be expected to continuously accelerate and improve the accuracy of the entire drug discovery process.

Digital platforms will significantly shorten research periods and continuously improve operational processes and experimental processes through an autonomous system. These platforms will also serve as a cornerstone for achieving an ultrafast drug discovery cycle in the future.

## Overview of a Digital Platform



NTT DATA's Vision of Future Drug Discovery Research: Ultrafast Drug Discovery Research Cycle Achieved Through Digitalization

# Chapter 4

NTT DATA's Case Studies and Efforts



## NTT DATA's Efforts Toward Digitalization of Drug Discovery

### Assets Required for Transformation of the Drug Discovery Process

The transformation of the drug discovery process described in the previous chapters is not a fantasy and is quite real. NTT DATA has persistently worked to conceptualize, develop, and implement services and solutions in diverse fields including life sciences and healthcare. We believe that, by synthesizing the knowledge and experience we have accumulated in this process, we can facilitate the resolution of challenges faced by pharmaceutical companies and together with our partners achieve innovation in the drug discovery process.

### Technological Elements Required to Pursue the Focus Points of Transformation

We believe that our solutions, LITRON, COTOLABO and the Data Infrastructure for Pharma, can contribute to our pursuit of the transformation's focus points presented in Chapter 3.

In Focus 1, achieving *sophistication of examination and analysis* will require having technology that can process a wide range of text from broadly diverse fields and in diverse formats, including patent information, experimental data, and internal reports, in addition to published journal articles. It will also require technology that can analyze information from these large amounts of text data while taking into account their context, and express

### Innovation Points in the Drug Discovery Process

**Focus 1: Sophistication of Examination and Analysis**

**Focus 2: Seamless Execution from the Development of Assays to Drawing Up of Experimental Designs**

**Focus 3: Improvement of Reproducibility Through Digitalization of Experiments**

**Focus 4: Improvement of Efficiency Through Prediction of Experimental Results**

the output in a form that enables researchers to interpret them such as in figures and tables. LITRON is a service that is able to learn even with only a small amount of data and extract contextual information from input documents in tabular form. This allows us to extract knowledge in a comprehensive manner from documents too large in volume for humans to read through and will therefore play an important role in pursuing Transformation Focus 1.

In Focus 2, achieving *seamless execution from the development of assays to the drawing up of experimental designs* will require an integrated data platform that enables the sharing of information and feedback throughout the experimental process. To accomplish this, we believe we can utilize the knowledge we have accumulated through the Data Infrastructure for Pharma as our solution for pharmaceutical companies.

In Focus 3, achieving the *improvement of reproducibility through the digitalization of experiments*, and in Focus 4, achieving *improvement of efficiency through prediction of experimental results*, will require the laboratory's digital twinning through accurate recording of manual experimental work and collection of data for all experimental environments. COTOLABO is an effort to digitally record and centrally manage/use all experimental data including data on the environment and actions inside the laboratory, and can prove a major step in pursuing Focus Points 3 and 4.

### NTT DATA Services and Solutions



A service that allows for the extraction of desired data from huge volumes of text data without prior learning

### COTOLABO

 A project for building a next-generation laboratory that digitizes and centrally manages/uses all experimental data

### Data Infrastructure for Pharma

A solution for the pharmaceutical industry that provides high performance, high security, and ease of external collaboration

## Case 1: LITRON

Natural language processing technology has seen more and more advancements in recent years and attempts are being made to extract useful information from text data in diverse fields. However, text analysis of business documents frequently involves industry-specific terms and specialized documents, requiring a great deal of time and effort for learning before starting analysis, which has prevented clients from utilizing the technology in their own businesses.

We have therefore developed a document reading AI solution, LITRON, that can be applied to business with just a small amount of work.

LITRON uses patent-pending technology to learn how to read documents by interacting with experts, thus eliminating the need to identify industry-specific expressions or learn a large volume of industry documents in advance. LITRON is able to start analysis promptly by learning industry-specific expressions and terminology in less time than was previously possible, which allows for its application over a wide range of business situations including manufacturing, finance, legal, and healthcare.



Structured Information

Other features of LITRON include:

- Extraction of structured knowledge from text
- Various analysis including prediction and classification based on structured knowledge.

LITRON is an *AI that can read text with high accuracy in a short time*. It understands the meaning of information while taking into account the context like we humans do, structures the important information from any document, and can even use that information to build predictive and analytical AI.

In the healthcare field, for example, we have successfully built an AI that predicts the results of experiments in the field of regenerative medicine by extracting highly accurate information from approximately 50,000 iPS cell-related journal articles. LITRON has also learned a large volume of package inserts to successfully identify the risk of concomitant use with an accuracy that exceeds that of experts (pharmacists). As seen here, LITRON is being used in a diverse range of analytical tasks that go beyond the simple extraction of data.

Disease Name	Location	Time
COVID-19	Wuhan	Dec. 2019
SARS	Guangdong Province	Mar. 2003
:	:	:

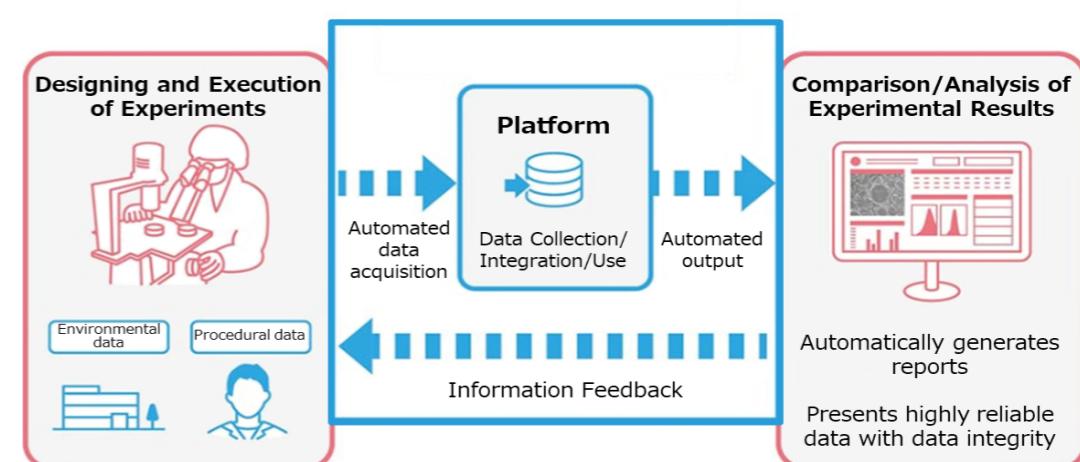
## Case 2: COTOLABO

Research in life science has seen cases where the lack of reproducibility and reliability of experimental data have not only led to inefficient research efforts but also to doubts about the research outcomes. Under such background, companies who agree on the importance of ensuring data reliability in life science research have gathered to initiate a joint effort named the COTOLABO project. With the goal of improving the efficiency and reproducibility of experiments conducted in laboratories in life science such as drug discovery and regenerative medicine, this project is working to build a next-generation laboratory that digitalizes and centrally manages/uses all experimental data.

In conventional laboratories, experimental records have been kept in handwritten notebooks or even just with the researchers' themselves, which gives rise to uncertainty about the records and creates an over-dependence on the knowledge of individual researchers. COTOLABO's next-generation laboratory on the other hand, will digitalize all information generated during experiments to achieve the following:

- Holding discussions based on quantitative, fact-based information
- Identifying factors for experimental success/failure that are not recognizable to humans
- Improving experimental reproducibility during the time period when introducing new technologies or relocating labs
- Optimizing and continuously improving actions during experiments and experimental resources

**COTOLABO Project**  
An initiative to build a laboratory that **digitalizes all possible experimental data** for management/use with the goal of **improving experimental efficiency and reproducibility**



## Automatic Extraction of Experimenter's Actions from Videos

The COTOLABO project comprises multiple PoCs in collaboration with other companies. As one of these efforts, we conducted a verification of a system that extracts and lists the actions performed by experimenters from video recordings of experiments in drug discovery.

To perform this verification, we installed two cameras in a safety cabinet (box-like experimental facility) at a laboratory to capture the experimenter's hand movements, and attempted to extract basic experimental actions such as holding a flask, pipette manipulation, and disinfection. The estimation of actions by AI was largely successful, and we were able to obtain suggestions on both tangible and intangible aspects to achieve even higher accuracy.

The acquisition of data through video images prevents the loss of reliability due to human errors in recording or forgetting to record data and also allows keeping a record of actions during experiments that could not be recorded in the past, as data to be analyzed. Acquiring data in this way will allow us to review the experimenters' actions later based on objective facts such as whether the experimenter conducted the experiment according to the designed procedure and whether there were any factors in the success/failure that we were not previously aware of.

### Case 3. Data Infrastructure for Pharma

Considering the characteristics of the pharmaceutical industry, there are three important requirements for a data analysis infrastructure for pharmaceutical companies. These three requirements are high performance, high-security data governance, and the ability to share data.

Based on the characteristics of the pharmaceutical industry, the following three elements were identified as important requirements for a data analysis infrastructure.

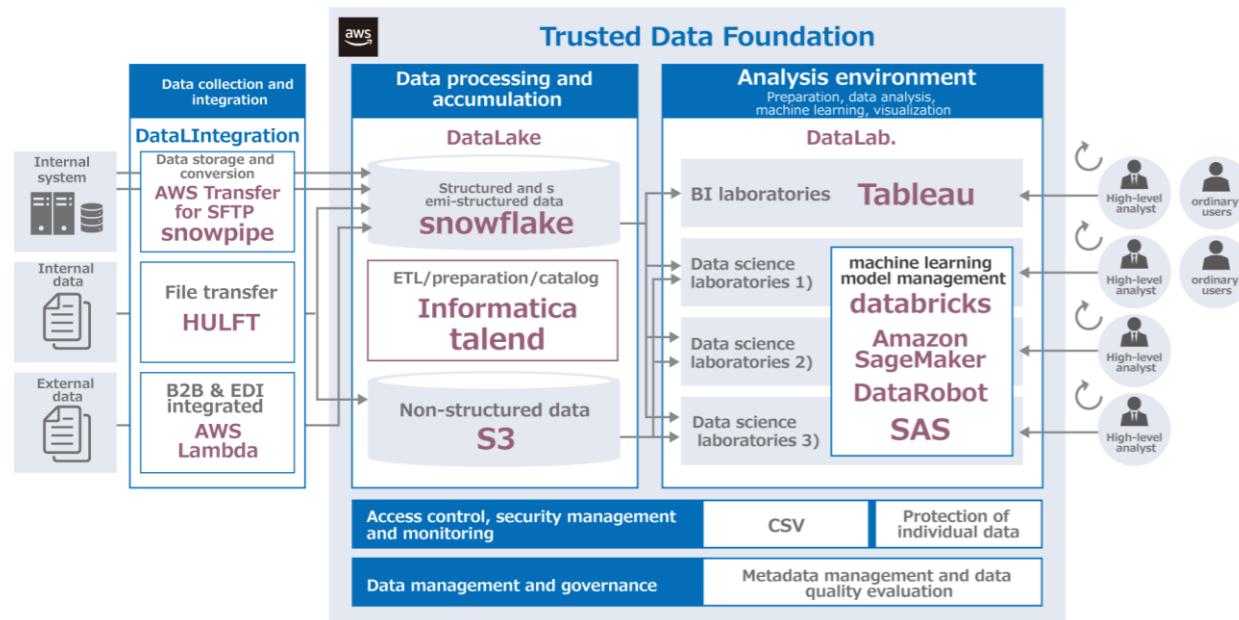
- (1) A high-performance platform capable of high-speed handling of large volumes of data such as RWD and image data such as experimental data
- (2) A high-security platform that is compliant with Computerized System Validation (CSV) and personal information protection which are essential in the pharmaceutical industry and also ensure data governance
- (3) A platform that is capable of sharing data easily while also ensuring security for collaborating with external parties such as academia, healthcare institutions, and partner companies

Based on this, NTT DATA offers **Data Infrastructure for Pharma** as a solution for the pharmaceutical industry that achieves high performance, high security and ease of external collaboration. This **Data Infrastructure for Pharma** optimizes several advanced solutions that are being utilized globally and turns them into an asset. In drug discovery, it will likely be utilized for target discovery using a large volume of omics data, and data sharing in industry-industry collaboration, among others.

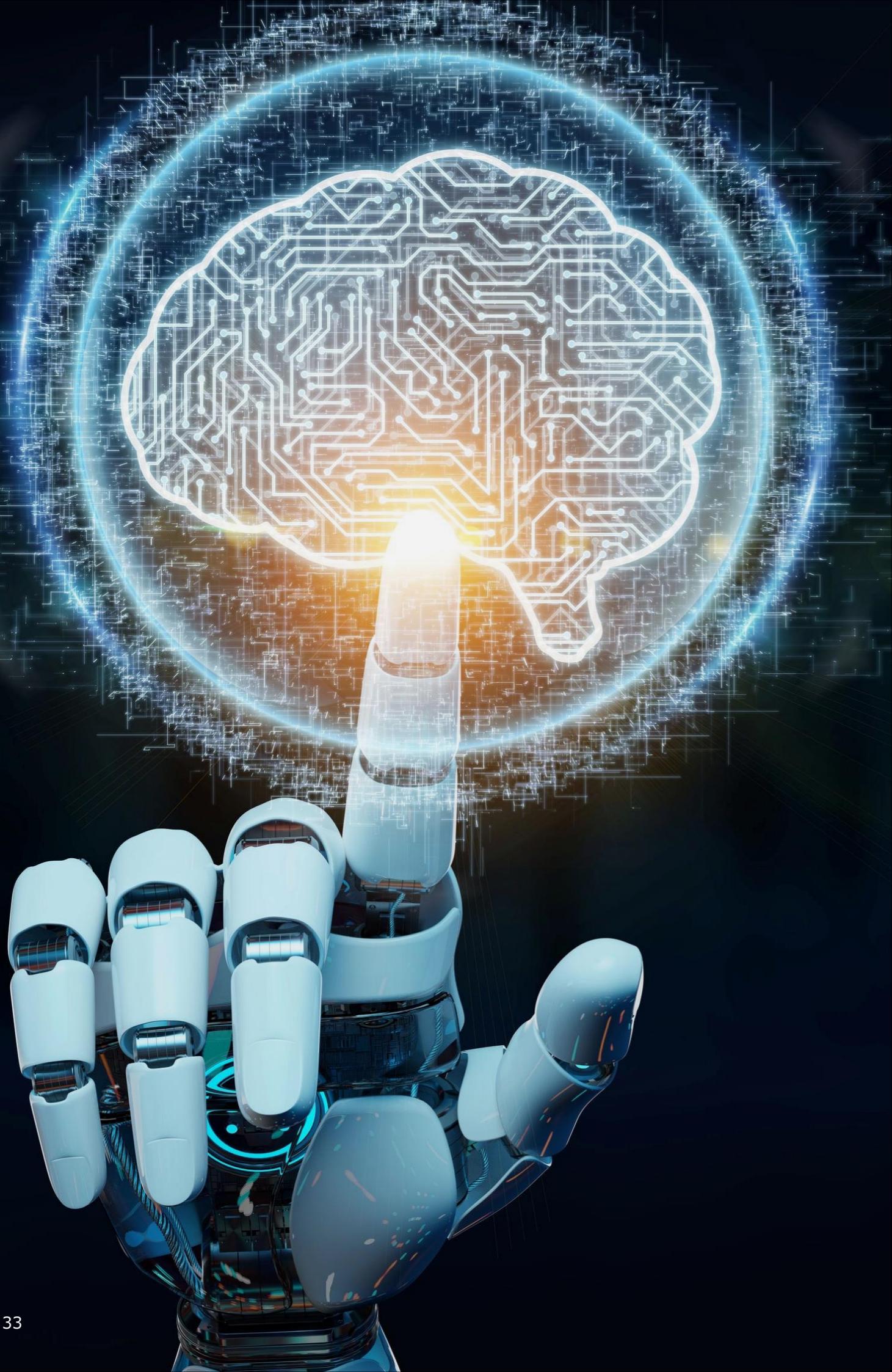
Data Infrastructure for Pharma is expected to bring the following benefits:

- Lower cost, shorter time, and higher quality than building a new platform from scratch
- Allows for the selection and phased introduction of technologies according to the application and budget
- Allows for the verification of feasibility and performance in a trial environment before building the actual platform

### Overall Image of "Data Infrastructure for Pharma"



NTT DATA's Vision of Future Drug Discovery Research: Ultrafast Drug Discovery Research Cycle Achieved Through Digitalization



**NTT DATA Corporation**  
**Pharmaceutical/Life Sciences Industry Drug Discovery Lab DX Team**



**Masato Hayama**  
Senior Manager  
Pharmaceutical & Chemical Division



**Tatsuya Motomura**  
Manager  
Consulting & Marketing Division



**Shun Yokota**  
Deputy Manager  
Pharmaceutical & Chemical Division



**Takeshi Ito**  
Deputy Manager  
System Integration Division



**Kaho Goto**  
Assistant Manager  
Consulting & Marketing Division

**Motohide Kato**  
Technology Consulting Sector

**Yui Yamaguchi**  
Technology Consulting Sector

**Yuta Ando**  
Pharmaceutical & Chemical Division

**Tomoyuki Hosono**  
Consulting & Marketing Division

**Ryota Aoki**  
Machinery,  
Electronics &  
Construction Division

**Marin Sakurada**  
System  
Integration  
Division

**Takanori Sato**  
System  
Integration  
Division

**Yumu Hirayama**  
System  
Integration  
Division

**Teruyoshi Hosokawa**  
Machinery,  
Electronics &  
Construction Division

For inquiries, please contact:  
**Yokota, Motomura**  
[life-sciences@am.nttdata.co.jp](mailto:life-sciences@am.nttdata.co.jp)