Digitally Transforming Life Sciences

Digital Transformation (DX) and Medical Experience (MX) Lead the Pharmaceutical Industry to New Possibilities

NTT DATA's Vision for the Future of Healthcare and Life Sciences

Introduction

Digital Transformation (DX) and Medical Experience (MX) Lead the Pharmaceutical Industry to New Possibilities

NTT DATA's Vision for the Future of Healthcare and Life Sciences

In recent years, pharmaceutical companies have been leveraging the latest digital technologies and data to achieve **Digital Transformation (DX).** IT is at the forefront of initiatives to realize business goals such as increasing corporate value and enhancing competitiveness.

For example, many pharmaceutical companies are promoting digitalization throughout their existing value chains. DX in the pharmaceutical industry strives to streamline processes such as R&D, manufacturing, sales & marketing, and related business management functions. Pharmaceutical companies are also working to create value through new initiatives such as Digital Therapeutics (DTx) and Digital Medicine in collaboration with IT and healthcare companies.

As an insight into DX, this whitepaper summarizes the “latest technology trends in the pharmaceutical industry,” presents “NTT DATA's vision for the future of pharmaceuticals,” and “NTT DATA’s focused solutions to enhance **Medical Experience (MX)**.”

Chapter 1 delves into the latest technological trends in the pharmaceutical industry using three broad categories. The latest trends are classified under **Personalized Medicine**, covering the needs of each patient. **Advancement in the Drug Discovery Process** and **Real-World Data/Real-World Evidence Utilization** which are vital for DX in the pharmaceutical industry.

Chapter 2 defines NTT DATA's vision for the future of the pharmaceutical industry, built on the latest technology trends outlined in Chapter 1. A patient-centered medical experience (MX) is introduced along with technology perspectives that enable the transformation of the pharmaceutical value chain.

Lastly, in Chapter 3, NTT DATA elaborates on its **solution capabilities** to address the demand for DX in the pharmaceutical industry. These capabilities are developed around the latest technological trends in the pharmaceutical industry and our vision for the future of pharmaceuticals (MX)."

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Chapter 1:
Latest Technology Trends in the Pharmaceutical Industry

1.1: Personalized Medicine
1.2: Advancement in Drug Discovery Process
1.3: Real-World Data (RWD)/Real-World Evidence (RWE) Utilization

1.1 Personalized Medicine

What is Personalized Medicine?

Personalized medicine optimizes decisions about the prevention, diagnosis, and treatment of a disease based on the individual's constitution, physical condition, and lifestyle. For example, with the advancement of genome analysis technology, it is possible to propose cancer treatments based on an individual's genetic sequence. This technology detects the patient's condition with high accuracy, prevents the disease from aggravating, and aims to maximize the effectiveness of treatment.

Benefits of Widespread Use

Patients benefit from the widespread use of personalized medicine. It enables effective treatment to patients who have not responded to conventional drugs and reduces its side effects. Furthermore, personalized medicine reduces unnecessary treatment by facilitating treatment planning based on patient characteristics and eases the economic burden on patients.

Its benefits also extend to pharmaceutical companies. Linking multiple diseases with the same genetic characteristics may allow clinical trials for complex diseases to proceed more efficiently[1] and allows drug development to proceed smoothly. By applying genomic analysis in single-subject clinical trials (N of 1 Trial), nucleic acid drug development for ultra-rare diseases can be promoted[2].

Challenges for Dissemination

Although there are elevated expectations from personalized medicine, there are equal number of factors challenging its growth.

In the R&D process, medical experts must interpret large volumes of patient data to understand the appropriate combination of genetic information and therapy. Highly knowledgeable personnel and extensive research facilities are essential for complex data analysis. For instance, genetic testing systems for cancer treatment require pathologists and laboratory technicians who perform sample quality control and sequencing, as well as bioinformatics specialists who perform accuracy control in data processing[3].

In the manufacturing of personalized medicine, companies produce a large variety of products in small quantities to respond to the individual needs of patients. Precise adjustment of supply and demand is required to achieve production at this level. It is also necessary to build flexible manufacturing lines and optimize logistics strategies to deliver personalized medicine to patients.

So, what approach can best achieve personalized medicine in response to these challenges?

In this section, we will introduce three initiatives that aim to enhance personalized medicine using technology. **Genetic analysis**, **3D printing**, and **drone delivery technology** address the challenges of high-mix low-volume production and logistics optimization.

1.1 Personalized Medicine

Initiative 1: Illumina - Advanced Genome Analysis Technology to Match Genetic Information with Treatment Plan

Genome analysis is a fundamental process in personalized medicine. Detailed analysis of a patient's genetic information can significantly aid in disease prevention and treatment. It can also streamline the process of diagnosis and finding the appropriate treatment, resulting in faster and more effective care. Furthermore, it may provide new treatments for diseases that were previously considered difficult to treat.

Illumina

Illumina's advanced next-generation sequencing and genotyping technologies are examples of genome analysis methods. Illumina has contributed significantly to the development of personalized medicine[6] for nasopharyngeal cancer, which is said to have a high incidence in Asian countries, and to research[7] the pathogenic mechanism of Behçet's disease, an intractable disease with a high incidence of nasopharyngeal cancer in Asian countries.

In partnership with global pharmaceutical companies such as Roche and Merck, we are also developing technologies for companion diagnostics and other diagnostics that will be indispensable in personalized cancer care[8][9].

The Decreasing Cost of Genomic Analysis and its Impact

The cost of genomic analysis has decreased dramatically in recent years[10]. As a result of lower costs, the drug discovery process is likely to change significantly in the future.

In the drug discovery process, companies will be able to obtain more genetic information cost-effectively, and broadly identify new drug targets quickly. Trial design will be optimized by selecting more eligible patients based on their genotypes and biologic characteristics. The improved trial design will shorten the duration of trials, improve the reliability of results, and reduce costs.

These factors may lead to faster identification of genes and mutations targeted by new drugs and faster development of useful new drugs.

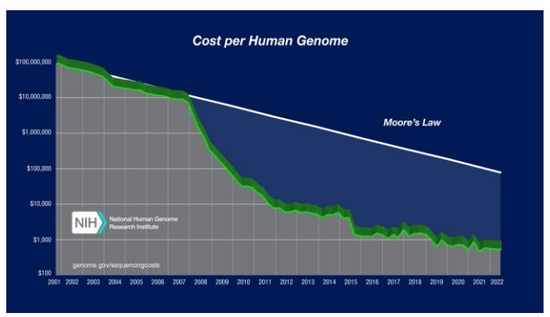
***Glossary**

Next-generation Sequencing (NGS)

Pow erful underlying technology that can simultaneously sequence thousands or millions of DNA molecules. The ability to sequence multiple individuals at the same time is a pow erful and fast process that has revolutionized individual medicine, genetic diseases, and clinical diagnostics[4].

Genotyping Technology

Genotyping data analysis tools can analyze the results of millions of markers and probes w hen multiple genomic targets may cause disease, detect sample outliers, and provide insight into the functional impact of genetic variation[5].



Courtesy: National Human Genome Research Institute
URL:DNA Sequencing Costs: Data (genome.gov)

Resources for Faster Development

To achieve faster development, manufacturers need to combine multiple resources at the same time. High-performance computing resources are essential to perform complex computational tasks quickly and effectively, such as processing data generated by genome sequencing. It is also desirable to have a large and robust database to store and retrieve vast amounts of genetic information.

When dealing with large volumes of genetic information, it is especially important that mechanisms are in place to protect patients' personal and sensitive data and that trial participants understand what they are consenting to (informed consent). Experts who use genetic analysis software and algorithms to interpret the data and identify drug targets will become more important.

Once these prerequisites are met, citizens would have access to genome-wide information in the future. By using genome-wide information, patients will be able to realize optimal treatment and disease prevention.

■ High-performance computing resources

■ Robust database and personal data protection

■ Experts in genetic analysis

1.1 Personalized Medicine

Initiative 2: Aprecia Pharmaceuticals/ FABRX Ltd. - 3D Printing Technology in Pharmaceutical Manufacturing

Originally, drug manufacturing was based on the premise of providing uniform medicines to patients. However, with the spread of personalized medicine, there is an increasing number of companies using technology to manufacture prescription medicines tailored to an individual's needs. One such technology that is attracting attention is 3D printing.

Aprecia Pharmaceuticals, a pioneer in the use of 3D printing, launched its FDA-approved SPRITAM® tablet in August 2015[11].

Since the FDA approval of SPRITAM, there has been an increase in the use of 3D Printing for pharmaceutical manufacturing. For instance, the M3DIMAKER is a 3D printer designed to produce personalized solid dosage forms[12].

M3DIMAKER was launched by FABRX Ltd. in April 2020, a spin-out company of University College London (UCL) in the United Kingdom. The printer is managed by a dedicated software, which allows tablets called Printlets to be adjusted and manufactured at the clinical trial site. The production is based on a chronological plan of the type, dose, duration, and procedure of the drugs registered beforehand. M3DIMAKER can respond quickly and flexibly to changes in patient demand and the development of new treatments, which has the advantage of enabling production of a large variety in small quantities and responding sensitively to market changes.

It is also possible to print "Polypills," combinations of active pharmaceutical ingredients based on individual patient needs. Since multiple drugs can be combined into a single tablet suitable for each patient, Polypills reduces the number of pills consumed per day. It helps prevent missed doses and improves treatment adherence. The drug's effect can be maximized by improving patient adherence.

SPRITAM

A treatment to control seizures in epilepsy. Powdered drug substances and liquids are outputs in a multi-layered structure. It also has the property of breaking down rapidly by adding only a small amount of liquid. SPRITAM is easy to consume for children, older patients, and for those with chronic digestive diseases.

Smartphone-based Medication Dispensing

In 2021, M3DIMAKER was successfully integrated with a smartphone to produce Printlets[13]. The size and shape of the medicine can be specified in the smartphone app according to patient needs. The medicine will be dispensed accurately using multiple photosensitive resins. This is an advanced example of the combination of smartphones and 3D Printing to realize personalized medicine.

Supply Chain Optimization Using 3D Printing

As this technology becomes more prevalent and the access to 3D printed medicines near patients becomes more realistic, inventory problems and supply constraints will be reduced, especially in areas with unstable transportation and distribution. Supply optimization to meet demand will be promoted, improving patient access to required medicines, particularly in personalized medicine and small-scale production.

1.1 Personalized Medicine

Initiative 3: Zipline - Drone Technology to Eliminate Disparities in Healthcare Access

In personalized medicine, it is important to design treatment approaches based on a patient's genetic and biometric information for timely access to appropriate medicines.

However, in some regions, transportation and distribution systems are not well developed. There may not be an established environment to enjoy medicines and medical devices based on treatment approaches.

Zipline provides rapid drone delivery to patients to address disparities in healthcare access due to underdeveloped distribution networks[14].

Zipline

Zipline built a drone delivery system with the mission of delivering essential supplies to people, especially in areas with limited infrastructure, access and during disasters.

Zipline currently operating in seven countries: Rwanda, Ghana, USA, Nigeria, Japan, Kenya, and Côte d'Ivoire, has flown over 60 million miles and delivered over 8 million products, including over 13 million vaccine doses[15].

Zipline's achievements in transforming healthcare logistics include the establishment of a national blood delivery network in Rwanda and the distribution of COVID-19 vaccines in Ghana. These initiatives are expected to pave the way for the rapid delivery of the latest laboratory and pharmaceutical products to remote areas.

It will also contribute to the local medical system by providing necessary medical supplies immediately in times of emergency and disasters.

Flexible manufacturing and distribution methods that cater to the diversifying pharmaceutical industry and the changing demand for rapid response are vital. In addition to conventional manufacturing lines, an increasing number of factories have lines that can be flexibly modified. The expansion of distribution methods such as 3D printing and drones is expected to further improve access and supply of personalized medicine.

Resources to Transform Drug Discovery and Improve Access to Medicine through Advanced Means of Manufacturing and Distribution

In this section, we have introduced technologies that solve the existing challenges in R&D, clinical trials, manufacturing, and distribution to realize personalized medicine.

Advancement in genomic technologies, such as those demonstrated in the Illumina case study, are lowering the cost of genomic analysis, and making acquisition of genetic information more efficient. Technological progress is enabling faster identification of new drug targets, and a more sophisticated selection of qualified patients. These factors will optimize clinical trial design, shorten turnaround times, improve reliability, and reduce costs, resulting in a transformation of the drug discovery process.

On the other hand, we saw the impact of technologies such as 3D printing and drones in drug manufacturing and distribution. 3D printing is becoming increasingly popular as a new manufacturing means to realize high-mix low-volume production in personalized medicine, such as the M3DIMAKER, which can be integrated with a smartphone to specify the shape and size of a medicine according to patient needs.

Furthermore, Zipline's efforts to establish a drone delivery network to overcome geographical limitations is expected to reduce medical disparities and the lack of accessibility. NTT DATA will continue to track the development of these technologies, which could become an important driver in the realization of personalized medicine.

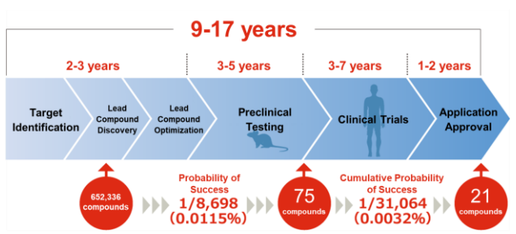
1.2 Advancement in Drug Discovery Process

What is Advancement in the Drug Discovery Process?

Improving the drug discovery process is essential for more efficient research to respond to the changing needs of patients. Transforming how we discover medicines can “increase the precision of drug discovery research itself,” as mentioned in the chapter about Personalized Medicine. This also “increases the speed with which new drugs can be approved and launched while reducing costs.” Advancement can further "streamline the drug discovery research process," and help in designing clinical trials for rare diseases.

To put the current drug discovery scenario into perspective, the challenge is in the diversification of modalities in the research process and the huge costs linked to longer research terms. The success probability of small-molecule drugs, which have been the mainstream until now, is said to be 1 in 300 million, but the success probability of biopharmaceuticals is even lower[1]. Moreover, it is said that the development of new drugs takes 9 to 17 years, 2 to 3 years for drug discovery research, and 3 to 7 years for clinical trials[2]. Considering the increasing difficulty of drug discovery research and its long development period, large investments are required from the research phase to the clinical trial phase.

In particular, the drug discovery research phase is a source of competitiveness for pharmaceutical companies. To conduct clinical trials with higher accuracy, it is important to identify drug targets with high contribution to disease mitigation and high success. Compounds with excellent drug efficacy and safety are created based on these drug targets.



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

Against this backdrop, efforts to transform existing drug discovery research into a highly efficient process may also be a factor in determining the survival of pharmaceutical companies.

Digital Transformation of Drug Discovery

Companies around the world are integrating the latest technologies in drug discovery research. This article highlights examples of pioneers that are taking the first steps towards digitizing drug discovery research:

- **Strateos**, which is working on Lab-as-a-Service/Robotic cloud lab
- **Insilico Medicine**, which is working on generative AI in life sciences
- **Moderna**, which is working on an IoT-enabled laboratory and cloud-based instrument data integration platform.

In response to the challenges of transforming drug discovery research into a high-efficiency process, IT research firm Gartner has reported[3][4] that the application of the latest technologies such as cloud-managed and remotely accessible scientific wet labs (Lab-as-a-Service/robotic cloud labs), AI in life sciences, IoT-enabled laboratories, and cloud integration of device data (cloud-based instrument data integration platform) will become a trend in drug discovery research in the near future.

Strateos – Transforming Drug Discovery with Lab-as-a-Service/Robotic Cloud Lab

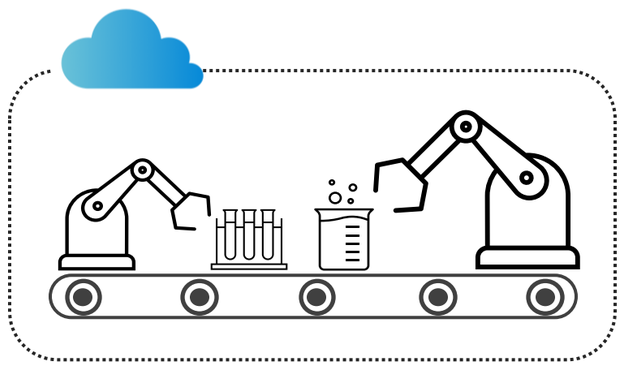
Offering remote research lab services in Silicon Valley with round-the-clock global access.

Strateos, a startup based in Silicon Valley, California, developed the SmartLab Platform. Pharmaceutical researchers can access the SmartLab Platform 24 hours a day from anywhere in the world and outsource their drug discovery work.

The company owns drug discovery studios in Menlo Park and San Diego, California. Their studio is equipped with state-of-the-art research equipment, including a robotic arm. Advanced software control via IoT provides a high-quality experimental environment that can automate various processes of drug discovery research that were previously considered difficult.

Researchers around the world can simply access the SmartLab Platform from their desktops and ask for the research they want. The automated experiments are conducted in remote Silicon Valley studios and returned as data. On average, research experiments took about 90% less time. This allowed researchers to focus on creative tasks such as hypothesis building, data analysis, and discussion[5].

In 2020, global pharmaceutical company Eli Lilly partnered with Strateos to launch the Lilly Life Sciences Studio Lab (L2S2) robotic cloud lab. By making its entire drug discovery process (compound design, synthesis, purification, analysis, and sample management) robotically automated and remotely controllable, Eli Lilly can use highly reproducible data in real time, independent of the experience and intuition of researchers. As a result, the evaluation cycle has been significantly reduced from a few weeks to a month, to two hours to a few days[6].



Transforming the Drug Discovery Scene with Robotic Cloud Labs

With Strateos’ SmartLab Platform, and widespread adoption of similar services, pharmaceutical companies have access to all the laboratory equipment they need without resource constraints. By speeding up the drug discovery process and increasing accuracy, companies will be able to engage in more diverse drug research.

The experimental environment, which can be accessed remotely 24 hours a day, will enable researchers to collaborate globally across countries, organizations, and fields.

1.2 Advancement in Drug Discovery Process

Insilico Medicine - Applying Generative AI in Drug Discovery

Insilico Medicine's Pharma.AI platform accelerates target identification and candidate design.

Companies are ramping up efforts to apply the latest AI in drug discovery. One notable example is **Insilico Medicine**, a company founded in 2014 with headquarters in Hong Kong and New York. Insilico Medicine uses AI to analyze and successfully generate databases for the search of new drug candidates.

Basic pre-clinical research in drug discovery involves identifying molecules related to the onset of a disease to be treated as drug targets (**target identification**), finding substances that inhibit the movement of these molecules, and designing new drug candidates (**candidate design**).

By using AI to develop drugs for the treatment of idiopathic pulmonary fibrosis, Insilico Medicine has been able to conduct clinical trials for about 18 months with a budget of approximately $2.7 million. The traditional method would have cost more than $400 million and required 6 years, but it took 1/3 of the pre-clinical process and 1/10 of the cost to reach the first phase of clinical trials[7].

Insilico Medicine used AI to speed up the analysis of previous research databases. New drug candidates were discovered in just 21 days as opposed to traditional timelines of two to three years. Furthermore, by using generative AI to design candidates, the company reached clinical trials in about 18 months.

Insilico Medicine's Pharma.AI[8] platform searched for the design of drug candidates for pulmonary fibrosis treatment. The platform is equipped with multiple AI models trained on millions of data samples. About 80 molecules were designed and synthesized, resulting in an unprecedented high success rate for pre-clinical drug candidates[9].

The Growth and Future Potential of AI Drug Discovery

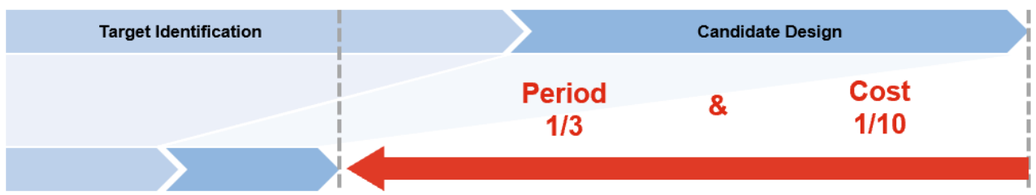
Major pharmaceutical companies around the world are also paying close attention to Insilico Medicine's initiatives and recent developments. Using their Pharma.AI platform, Insilico Medicine is collaborating with pharmaceutical and biotechnology companies such as Pfizer, Astellas, Johnson & Johnson, Sanofi, and Taisho Pharmaceutical[10][11].

Other companies have also recently followed suit to advance AI drug discovery efforts and have achieved results. For example, Takeda Pharmaceutical could use AI to select potential compounds for psoriasis treatment in a short span of six months.

XtalPi, headquartered in Shenzhen, China, used AI to speed up its chemical formulation for the treatment of COVID-19. The FDA approved the formulation in just two years.

According to research firm Deep Pharma Intelligence, AI-led drug discovery companies have more than tripled their investment in the past 4 years, reaching $24.6 billion in 2022.

Given this exciting trend of AI in drug discovery, integrating the latest AI technologies into research frameworks will be a breakthrough in accelerating R&D processes.



Moderna – Leveraging its mRNA Platform to Revolutionize Personalized Medicine

Ushering in a new era of digital-native pharmaceutical companies.

Moderna, founded in 2010 in the United States, was one of the first companies to make a COVID-19 vaccine. Moderna is developing mRNA vaccines in a state-of-the-art infrastructure environment.

mRNA is a molecule that acts as a blueprint for making proteins by copying information from genes. Moderna has adopted an mRNA platform strategy to develop all its drugs and vaccines using mRNA[12]. mRNA, which can be made by simply changing the sequence of bases and using the same raw materials, can be applied to the development of a wide variety of drugs. It can be easily digitized, thereby shortening development times, and reducing development costs. mRNA development methods are expanding beyond COVID-19 vaccines, with the market expected to grow to $23 billion between 2028 and 2035[13].

Moderna is in the process of applying its mRNA technology for cancer vaccines, and a new study shows that a personalized vaccine developed in collaboration with Merck protects against the recurrence of advanced skin cancer (melanoma) for up to 3 years[14].

Underpinning Moderna's mRNA platform strategy is an investment in innovative infrastructure. To digitally transform Moderna's overall operations, the company is migrating and integrating all their internal data into a cloud infrastructure. To enhance the digital environment, the company also promoted automation with the introduction of robotics to conduct experiments and tests without human intervention. Based on the large amount of data obtained and accurate analysis, the mRNA platform operates by rotating PDCA cycles at high speed.

Moderna's model will be a reference for the future of pharmaceutical companies. **Digital solutions** and innovative platforms like **mRNA** will solve issues related to development time, inflated costs, and the search for drug targets.

1.2 Advancement in Drug Discovery Process

Transformation as the Way Forward in Drug Discovery Efficiency

For most pharmaceutical companies, the difficulty of drug discovery research and huge R&D costs associated with long research periods create a bottleneck in drug development.

The pharmaceutical industry is challenged with a common goal of transforming drug discovery research into highly efficient processes. Companies that are actively investing in cyber transformation using the latest cloud and AI technologies, coupled with physical transformation through the development of peripheral environments such as IoT laboratory facilities will be best suited to navigate the changing trends of the pharmaceutical industry.

In conclusion, many companies are advancing to digitize drug discovery research, including cloud lab company Strateos, AI drug discovery company Insilico Medicine, and digital native company Moderna.

1.3 Real World Data (RWD)/Real-World Evidence (RWE) Utilization

What is RWD/RWE?

Pharmaceutical companies are utilizing RWD to promote personalized medicine based on genetic analysis for regulatory approval, and to provide useful insights (RWE) to confirm the efficacy of drugs. The U.S. Food and Drug Administration (FDA) defines RWD as data on a patient's health and treatment that is routinely collected from various sources[1]. Medical data classified as RWD are obtained in routine clinical practice, and are representative of dispensing prescription data, insurer data, electronic medical record data, and outcome data obtained from clinical practice[2].

Status of RWD Utilization

RWD is used in the medical sector to understand the efficacy and safety of drugs under actual conditions of their use and to calculate the market size when developing new drugs. As of April 2022, the number of new drug applications using RWD over the past 5 years was 17 in the United States, 11 in the EU, and 1 in Japan, and there are fewer applications in for drug discovery and development[3].

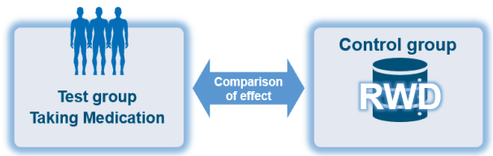
As the accumulation of outcome data (physician comments, laboratory values, and medical documentation) increases, RWD can be further applied in the pharmaceutical value chain apart from drug discovery and clinical trials.

Expectations from RWD Utilization

The clinical trial phase presents various challenges to pharmaceutical companies, such as the difficulty of trial recruitment, especially in trials for cancer and rare diseases. When conducting clinical trials for a new drug, it is often difficult to recruit sufficient trial subjects because the disease is rare. To address this issue, RWDs will facilitate randomized controlled trials (RCT) using outcome data based on clinical practice and prescription data from trial subjects (including hospitals). The implementation of RCTs using outcome data, although less accurate than data collected for clinical trials, is expected to be sufficient to proceed with trials efficiently by using RWDs to supplement the trial data.

Pharmaceutical companies, physicians, and governments are optimistic on the use of RWDs. Physicians can improve the efficiency and accuracy of diagnosis and treatment by using RWDs. Governments are looking to leverage RWD in medical policy evaluation and countermeasures in response to the recent trend of evidence-based policies (EBP)[4]. RWDs can also aid cost-effectiveness evaluations for applications for clinical development of drugs, and negotiations on insurance reimbursement and drug prices.

Utilizing RWD as a control



Using RWD presents multiple opportunities in drug development, policy, and treatment outcomes. However, it is also challenged with the appropriate collection and usage of outcome data. Obtaining data in a format suitable for analysis, and issues related to the protection of personal information, such as consent for data acquisition and anonymization processing add roadblocks in the process.

The following section highlights various initiatives and solutions that collect and use RWDs to tackle these challenges. Alliances of RWD companies are promoting the use of RWEs through outreach to regulatory authorities.

1.3 Real World Data (RWD)/Real-World Evidence (RWE) Utilization

PRiME-R – Developing Next-gen Medical Care Utilizing RWD

RWD accumulation and utilization in collaboration with pharmaceutical companies.

Established in 2020, **PRiME-R** promotes industry-academia collaboration on RWDs and contributes to the development of next-generation medical care based on better treatment.

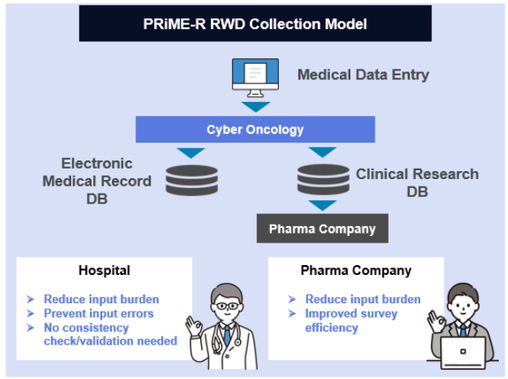
For example, in 2023, PRiME-R collaborated with pharmaceutical companies to develop a new model that uses RWD for post-marketing surveillance (PMS), improving the efficiency of drug use-results surveillance and reducing costs[5]. PRiME-R developed an RWD collection model for use in post-marketing drug use-results surveillance. The model operates on data collected by CyberOncology, an electronic medical record information entry support system.

Challenges of RWD Accumulation

When a new drug is launched, pharmaceutical companies conduct use-results surveys to track its safety and efficacy. In previous surveys, healthcare professionals had to re-enter clinical data in multiple capture systems (EDCs). Drug companies relied on medical records to gather the necessary information for the survey. However, this process has been challenging for both medical institutions and drug companies. It requires significant time and effort to input data, check for data accuracy, and make inquiries.

Prime-R's RWD Collection Model

The new RWD collection model employs CyberOncology, an input support system that standardizes, structures, manages, and integrates RWD in daily clinical practice. From the accumulated data, the information necessary for the use-results survey is directly extracted, and any additional information can be input. The new RWD collection model is expected to reduce the burden of data entry and management on medical institutions. It removes the need for duplicate data input and reduces survey costs while providing high quality.



Leveraging Generative AI

Additionally, PRiME-R is working to collect unstructured medical information in a structured manner using Generative AI to support drug discovery and analysis in clinical research[6]. The data collection process specifically targets data matching clinical items accumulated from various sources contained in electronic medical records, such as explanations to patients, audio data at in-hospital conferences, and more. The information is then categorized in an appropriate format and accumulated as structured data.

Widespread Use of RWD in Drug Discovery and Clinical Trials

A study to investigate the efficacy, safety, and treatment status of a combination therapy of Opdivo with chemotherapy in patients with previously untreated, advanced, or recurrent gastric cancer was conducted at 30 medical institutions in Japan. The joint study by PRiME-R, Ono Pharmaceutical Co., and Bristol Myers Squibb utilized standardized/structured RWD for daily cancer treatment.

Based on the accumulated and structured electronic medical record information, several pharmaceutical companies are exploring the use of RWD in drug discovery and clinical trials, areas where it has not been applied to date.

With the advancement of digitalization, it is expected that RWD will be utilized in more upstream areas to collect data and utilize it in drug discovery and clinical trials.

Real-World Evidence Alliance Formed to Promote RWE Across Industry and Regulatory Authorities

Consortium of 10 companies leading regulatory outreach and lobbying initiatives.

10 RWD companies, including Aetion, Flatiron, IQVIA, OM1, Optum, Syapse, Syneos Health, TEMPUS, Verana Health, and Verily, formed the RWE Alliance in 2021 to reach out to the FDA and other regulatory authorities[7].

The Real-World Evidence Alliance's main objectives are to encourage the use of RWD to validate drugs; create a forum for discussions between the FDA and the RWE Alliance; promote transparency in marketing authorization standards using FDA RWE; and advocate for the superiority of RWD over conventional clinical trials[7].

Continuous Lobbying for Regulatory Backing

As a result of ongoing lobbying by the Real-World Evidence Alliance, the FDA is moving in a more flexible direction to utilize RWD. In September 2023, the FDA released a draft guidance entitled, "Demonstrating Substantial Evidence of Effectiveness Based on One Adequate and Well-Controlled Clinical Investigation and Confirmatory Evidence". It also addressed the handling of evidence, including RWD/RWE, and flexible use of RWD[8].

The regulatory approval of RWD use varies from country to country. However, given the ongoing lobbying activities, it is expected that players will continue to reach out to regulatory authorities to benefit from RWD use. As a result of these trends, widespread use of RWD will be widely implemented in society.

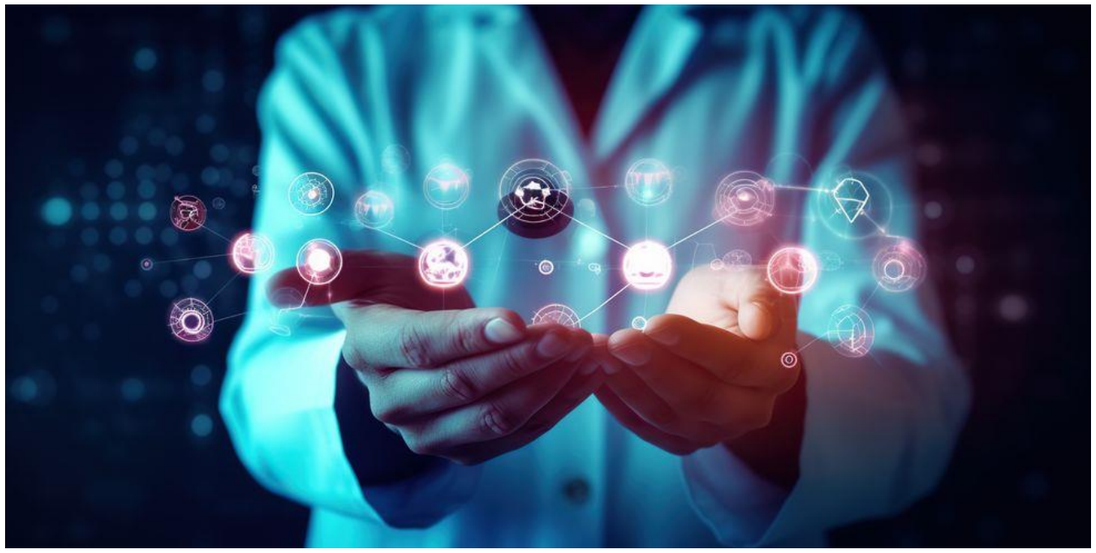
1.3 Real World Data (RWD)/Real-World Evidence (RWE) Utilization

IT Maturity and Regulatory Framework

In the use of RWD/RWE, data collection and usage are primary issues that need to be addressed. The collection of data should be in a form that is easy to use, and in adherence to the laws and regulations concerning personal information in each country.

Technical factors and the rules prescribed by regulatory authorities for the use of RWD determine the implications of each case. IT maturity will lead to more accurate RWD collection, an increase in the volume of data, and the advancement of AI analysis technology.

As we continue to build more use cases and applications for RWD, its role in drug discovery and clinical trials is becoming increasingly significant for pharmaceutical companies.



1.4 Summary

In this chapter, we have gotten a deeper understanding of how new-age technologies are transforming the pharmaceutical industry under three broad keywords and trends: **Real-World Data/Real-World Evidence Utilization, Advancement in Drug Discovery Process,** and **Personalized Medicine.**

Firstly, we introduced the technologies that are enabling future-ready solutions in R&D, clinical trials, manufacturing, and distribution to realize personalized medicine. IT's role and impact on various aspects of drug discovery, research, and outcomes were emphasized with specific cases and companies.

We have reviewed the recent growth and potential of genome analysis with the case of a company (Illumina) that uses advanced genome analysis technology to match genetic information with treatment. From the context of pharmaceutical manufacturing and distribution, we have seen the potential of IT to enable personalized medicine. The latest use cases of 3D printing (Aprecia Pharmaceuticals/FABRX Ltd.) and drone delivery (Zipline) are amplifying the reach of necessary medicines by manufacturing them closer to patients and eliminating the problem of physical access.

The advancement in drug discovery process delved into the innovation of drug discovery and AI, including cases from Strateos and Insilico Medicine, which are working on cloud labs and AI platforms, and Moderna's digital-native initiatives. To transform drug discovery research into a highly efficient process, we require cyber-transformation and physical transformation to be promoted in parallel.

Lastly, in Real-World Data/Real-World Evidence utilization we examined the larger role of data in enhancing drug discovery and clinical trials through PRiME-R's efforts to utilize RWD, and the Real-World Evidence Alliance's outreach to regulatory authorities. Regulatory outreach and building a framework of rules will further encourage the use of RWD in core areas of pharmaceutical companies.

Continued Efforts in Business, Technology, and Regulation to Enhance Healthcare Delivery

NTT DATA believes that technology is already revolutionizing pharmaceutical companies and their business models, and the pace will accelerate progressively.

In this situation, the key is to set a vision for the future that utilizes IT to maximize the benefit for every patient. To achieve this vision, it is essential to transform business models through cross-industry collaboration between IT companies, medical institutions, and pharmaceutical companies. Implementation of the latest technologies such as Gen AI, smart labs, and genome analysis will continuously encourage businesses to promote transformation and innovation.

Rapid development of new drugs, reduction of R&D costs, and the provision of an enhanced medical experience to every citizen will be prioritized along with efforts to address business, technology, and regulatory challenges.

Chapter 2:
NTT DATA's Vision for the Future of the Pharmaceutical Industry

2.1: NTT DATA's Vision for a Patient-centric Medical Experience

2.2: Upgrading the Pharmaceutical Value Chain

2.1 NTT DATA's Vision for a Patient-centric Medical Experience

What is Patient Centricity?

The importance of patient centricity cannot be ignored in defining the future of pharmaceuticals and healthcare. According to the Japan Pharmaceutical Manufacturers Association, it is, **"to incorporate the voices of patients, obtained directly or through their families or patient organizations, into drug development - drug development using the patient's voice."**

Patient centricity in corporate activities can be understood as, "**the initiative in pharmaceutical development which incorporates patients' voices throughout the process, from conceptualizing to conducting clinical trials, and through approval and application phases. Additionally, it encompasses corporate activities that respond to the expressed needs of patients, addressing their desires to know** [1]."

Innovation in Patient-centric Medical Experience (MX) through Medical DX

"Delivering information effectively to patients while capturing the individual voices of each patient and incorporating them into product development."

Digital technology excels in the feedback cycle; in other industries, such changes are already under way. For example, in video distribution, Netflix uses digital technology to capture users' lifestyles and interests. This data enables the provision of video on a variety of devices, numerous content choices, and recommendations that ultimately transform the video experience for the viewer. It is possible to view this digital megatrend as promoting a transformation of the experience based on a human-centered philosophy.

From this aspect, the evolution of digital technology will become an important driver for realizing patient-centered medical care (individualized medical experience seamlessly connected from the perspective of the individual). The key role of medical and pharmaceutical players in the future is to bring about innovation in the patient-centered medical experience (MX) through medical digital transformation (DX).

To achieve MX innovation, pharmaceutical companies need to realize innovative treatments such as personalized medicine and administer these treatments in a timely, effective manner. It is necessary to strengthen the digital capabilities of the pharmaceutical value chain, which consists of drug discovery research, clinical trials, and the supply chain, in terms of individual steps and using RWD across the entire value chain.

2.2 Upgrading the Pharmaceutical Value Chain

Advantages of Technology in Drug Discovery Research

There are several advantages of introducing digital technology in drug discovery research.

Firstly, the integration and analysis of medical data using evolving bioinformatics has the potential to create innovative treatments. By analyzing vast amounts of patient data, genetic information, and clinical trial results using digital technology, unique trends and treatment responses can be extracted.

A suitable example of this is the genome analysis technology mentioned in Chapter 1. By analyzing the genomic information of individual patients, we can predict genetic predisposition to diseases and response to treatment. This will allow existing medicines to be reused in different groups of patients and will advance the development of personalized therapies. At the same time, comprehensive analysis of patients' genetic and clinical data will facilitate the development of novel medicines that act on specific targets.

Digital Twin Lab – A Virtual Research Environment

One of the goals of digitalization of drug discovery research is the creation of a digital twin lab.

A digital twin lab is a virtual environment that digitally reproduces all the elements of a real lab. It includes equipment, materials, and human procedures digitized using various sensors, in a realistic and thoroughly automated setting.

Ultra-fast DMTA in a Digital Twin Lab

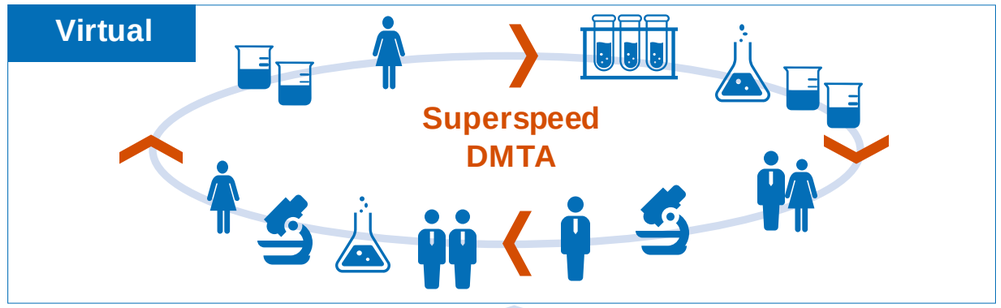
A brute-force approach to drug discovery was previously impossible due to physical limitations. In a digital twin lab, however, it can be implemented as a virtual simulation across processes, from pathway discovery to target identification, candidate discovery, screening, pharmacology, kinetics, and safety. By conducting experimental simulations that are independent of human bias and including a wide range of low-success candidates and combinations, new candidates and unconventional methods can be discovered.

From here, the experimental instructions that receive the simulation results from the virtual lab are automatically linked to the highly automated real lab. The number of experiments and the time required to conduct them in the real lab are also significantly reduced. Well-defined hypotheses results are narrowed down from multiple trial-and-error simulations conducted virtually.

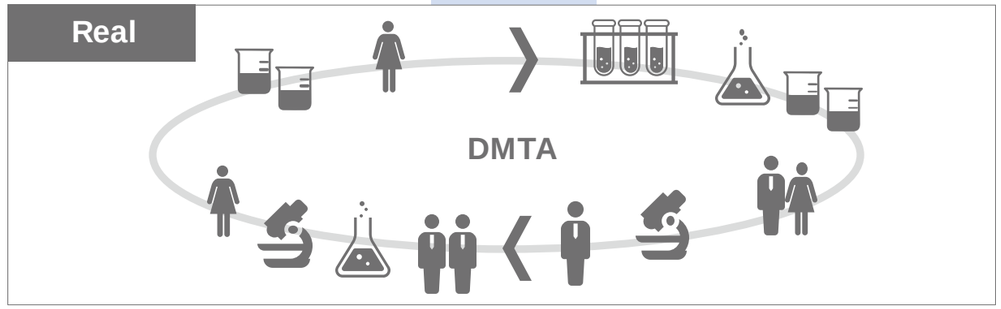
The work of researchers is evolving to focus on more creative methods and communication techniques. Even when individual experiments are required, using automated lab facilities will enable faster trial-and-error searches.

These ultra-fast DMTA cycles across real and virtual environments will transform drug discovery into a more efficient process. It augments the efficiency of human resources and materials and shortens the time to discovery of new drugs.

The Future of Drug Discovery Research Activity



Implementing Digital Twins



2.2 Upgrading the Pharmaceutical Value Chain

Challenges to Accelerating Clinical Trials

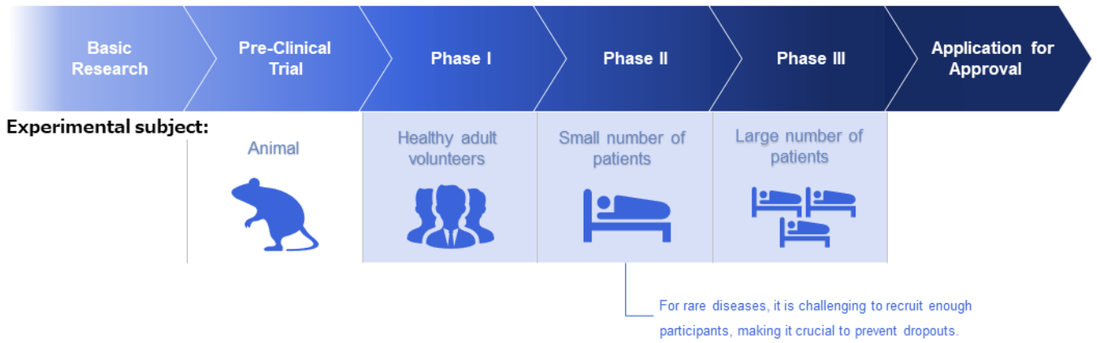
Acceleration of clinical trials is one of the core challenges to providing innovative therapies at an early stage and enhancing MX.

To achieve a speedy clinical trial in the case of rare diseases, the priority is to secure patients who are willing to participate and to prevent dropouts. The limited number of patients in a trial creates a problem of not attracting enough subjects.

Even if participants are recruited, it may be difficult to collect data, track the health status of patients and the effects of treatment.

There is an increased burden on patients to attend the medical facility or undergo ongoing testing for the trial, which can lead to fluctuations in patient motivation, dropout from the trial, and accuracy issues in the data collected.

■ **Pharmaceutical workflow from research to approval review and post-marketing**



Increasing Number of International Clinical Trials to Secure Human Subjects

International clinical trials to recruit human subjects from multiple countries have been increasing in recent years to study rare diseases and specific genotypes[1][2]. It may be difficult to conduct phase III clinical trials for diseases with a small number of patients. Therefore, international cooperation is essential to promote a rapid clinical trial process while prioritizing safety.

Decentralized Clinical Trials (DCT) and Digital Drugs Enable Remote Participation in Clinical Trials

Continuous hospital visits and adherence to treatment are fundamental to assess the health status and treatment effects of trial participants. However, this can be a significant burden on trial participants, resulting in dropouts from the trial and poor quality of trial data.

Decentralized Clinical Trials (DCT) can reduce this burden on patients. DCTs allow patients to participate in trials from home or in remote locations without having to visit a medical facility.

Accurate collection of patient health information and medication status is an important prerequisite for DCT. A swallowed sensor can be used to provide accurate monitoring as it allows collection of biological information from within the body.

For instance, the gas capsule developed by Atmo allows biomarkers to be measured at the sites of gas generation in the digestive system. It is equipped with a gas sensor and covered with a special membrane that prevents stomach acid and digestive juices from entering and allows only gas to pass through its body. The information obtained from this sensor can detect gastrointestinal abnormalities, inflammation, indigestion, changes in the gut microbiota, dynamics, and movement patterns, as well as evaluate the response of the digestive system to specific foods. The sensor helps diagnose diseases and symptoms of the digestive system. The collected data is sent to a pocket-sized receiver, which is then structured to be linked to the cloud for aggregation, analysis, and diagnosis[3].

DCTs can flourish with the use of innovative digital solutions like swallowable sensors that can accurately link patient clinical trial data to medical institutions.

Expanding the scope of DCT will prevent patients from dropping out of clinical trials due to burdens such as hospital visits and continuous testing and will contribute to the acceleration of clinical trials.

2.2 Upgrading the Pharmaceutical Value Chain

Enabling the One-to-One Supply Chain

In patient-centered medical care, delivering medicines quickly is a high-priority requirement. A flexible and optimized process from production to distribution, or a one-to-one supply chain, is essential to meet the increasing complexity of manufacturing requirements. A one-to-one supply chain is characterized by integrated supply chain management, optimization of production systems, and advanced traceability.

Optimizing Production Systems for Speed and Variety

The first and most important aspect of realizing a one-to-one supply chain is the optimization of production systems. Diversifying production facilities and systems enables the production of multiple varieties of the same product. A flexible line design and configuration are necessary to produce multiple varieties of drugs that are tailored to the individual constitution and genome of the patient.

It is also beneficial to refine planning to accommodate changes in the frequency of variety switching. Inventory and distribution status of individual varieties will lead to optimized production lots. We will be able to manufacture and distribute a larger variety of pharmaceutical products with an integrated supply chain.

Improved Traceability Enhances Reliability and Trust

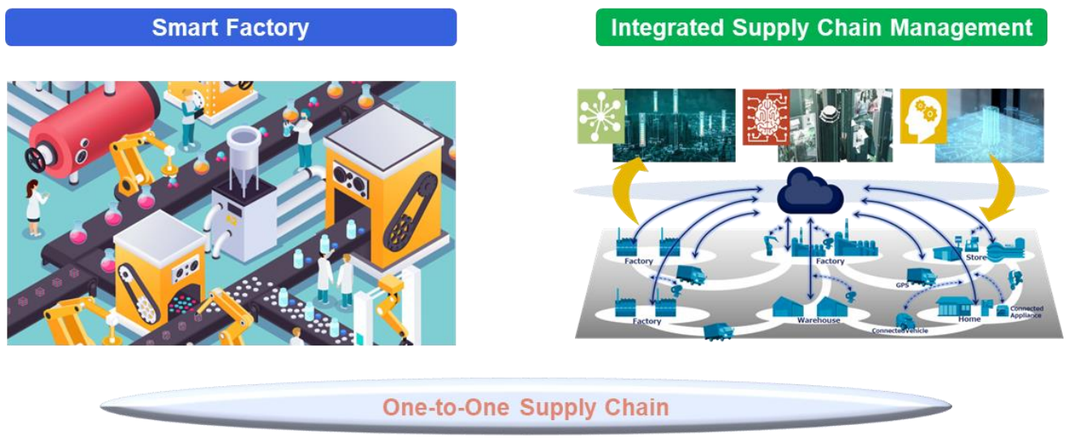
The next step in realizing a one-to-one supply chain is the advancement of traceability. This will benefit both patients and pharmaceutical companies. Improved traceability can capture the lot-by-lot tracing of pharmaceutical products and track the distribution process to end-use hospitals, doctors, and patients.

Advanced traceability will give patients peace of mind and the assurance of safety through quality control and improved transparency. On the other hand, pharmaceutical companies can create distribution plans and optimize distribution channels by providing centralized visibility of distribution history.

Smart Factory and Integrated Supply Chain Management

One way to realize the production structure required for a one-to-one supply chain and to optimize production planning is to employ the concept of **Smart Factory**. It enables advanced manufacturing through simulation, automation, and autonomous relearning. By incorporating sensors and IoT devices into the manufacturing line and collecting and analyzing data in real time, productivity and quality of products can be improved.

Additionally, integrated supply chain management using data and advanced analytics is essential to improve traceability of the distribution processes. Transformation of production systems and changes in the operations of stakeholders such as wholesalers, can lead to optimized operations in the ecosystem from production to post-medication safety management.



Need to Strengthen Digital Capabilities in the Pharmaceutical Value Chain

We have discussed the need to analyze patient data collected at each step of the pharmaceutical value chain, including research, clinical trials, manufacturing, and distribution. This data further shapes evidence-based treatments and helps introduce digital technologies to improve efficiency.

It is essential to promote optimization of internal systems across the value chain to facilitate the coordination of individual operations and further improve productivity.

For example, to manage and use the vast amount of data collected, we need a platform that is guaranteed to provide performance and security. When dealing with particularly sensitive information such as patient data, we need to encrypt the data and strictly control its access in consideration of legal regulations and patient trust.

It may be difficult for pharmaceutical companies with a global presence to share data in different systems across regions. As a countermeasure, it is possible to achieve global data linkage and cost reduction by linking systems throughout the company and providing standardization and interoperability.

In addition to strengthening excellence at each step of the pharmaceutical value chain, companies need to enhance their digital capabilities across operations and systems in a balanced manner.

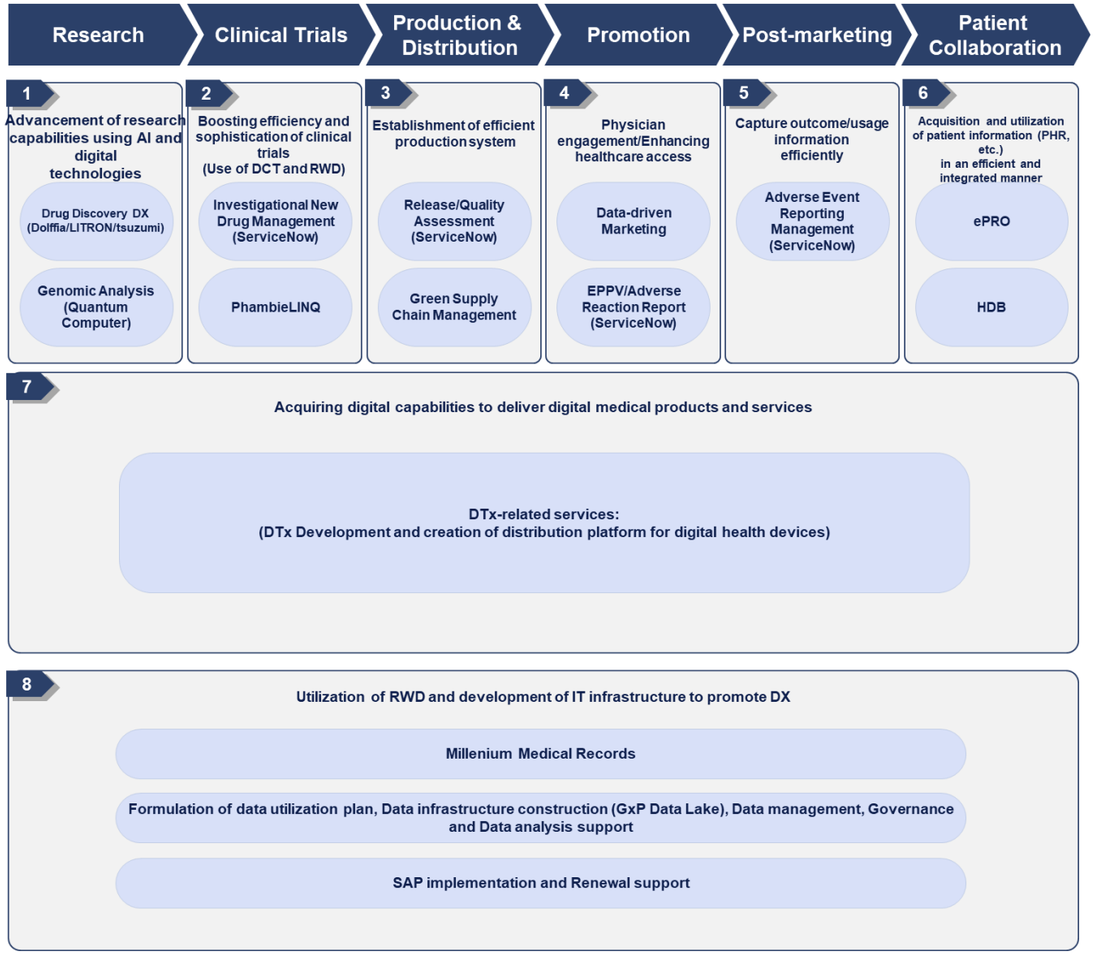
Chapter 3:
NTT DATA‘s Focused Solutions to Enhance MX

3.1: Advancing Drug Discovery Research with AI
3.2: Accelerating Clinical Trials: Collection and Use of Outcome Data
3.3: Establishing an Efficient Supply Chain
3.4: Common Value Chain Solutions

NTT DATA's Pharmaceutical Capabilities

NTT DATA has conceptualized and implemented an array of solutions for pharmaceutical companies worldwide. By integrating this knowledge and experience, we aim to solve the pharmaceutical industry’s challenges and enhance MX to build a patient-centered world.

In this chapter, we will introduce some of NTT DATA’s solutions and capabilities co-created with pharmaceutical companies to elevate MX. Our approach prioritizes **advancing research capabilities through AI**, **streamlining clinical trials**, **establishing efficient supply chains**, and **common value chains** to achieve MX transformation.



※ 1-6 ： Solutions/Capabilities for each Value Chain

※ 7,8 ： Solutions/Capabilities for Whole Value Chain

3.1 Advancing Drug Discovery Research with AI

Foundation of Advanced Drug Discovery Research

A highly accurate and timely research process based on genome analysis technology and digital twin labs defines the future of drug discovery research. As digital technology continues to evolve, drug discovery research will progress exponentially. NTT DATA is working with global pharmaceutical companies to apply technology to the drug discovery research process, and particularly, to provide **solutions to enhance the sophistication of drug discovery research**.

Advanced Research Needs

To find specific targets and validate them are essential parts of the drug discovery research process, but it can be challenging. Researchers pursue multiple sources of information, such as article websites and internal documents to obtain new research ideas. However, such searches can be time-consuming and may not yield the desired information.

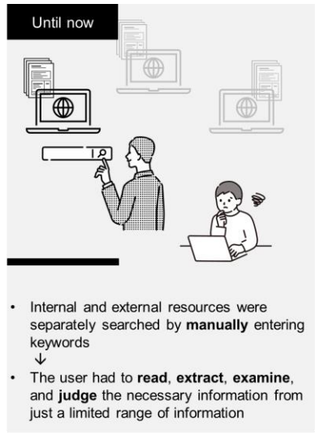
The **burden and lack of coverage** on researchers in R&D must be addressed to facilitate a more efficient and precise drug discovery process.

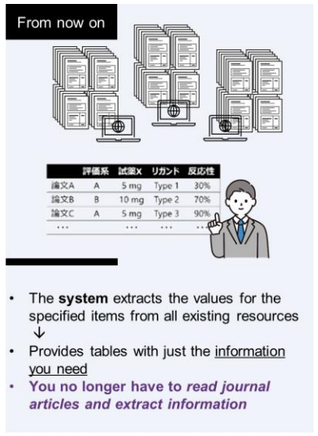
Text Analytics Solutions

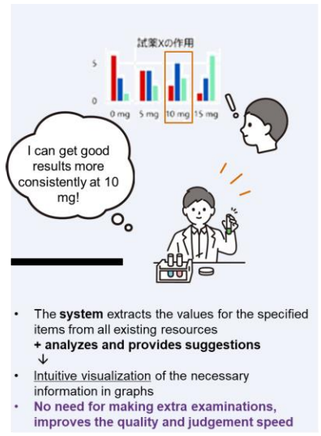
Natural language processing AI technology has evolved over the years, and attempts are being made to apply this technology in diverse fields.

It is vital to have technology that can process a wide range of text in all fields and formats, including patent information, experimental data, internal company reports, and article data. In addition to exploring and extracting information, NTT DATA uses natural language processing AI to automatically structure and chart the extracted information to provide suggestions and hypotheses to researchers.

NTT DATA's AI-based tools simplify and transform daily processes across industries, and we are tailoring these solutions to create impact in pharmaceuticals. '**Dolffia**,' is being used in Europe as a text and data analysis solution, '**LITRON**,' is equipped with Generative AI, and '**tsuzumi**,' is characterized by lightweight and multimodal features, complementing the advanced data analysis requirements in the drug discovery process.







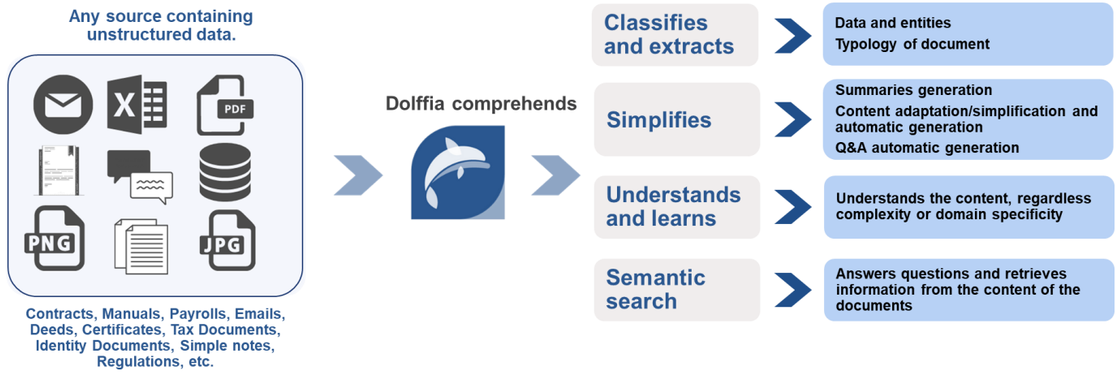
- **Dolffia**[1]

Dolffia is an AI text analysis solution that can automatically classify various types of documents and extract important information with high accuracy and speed.

NTT DATA worked with Spanish pharmaceutical company Almirall, to extract the information needed by trainees on the causes of atopic dermatitis from various medical papers. In this project, we first identified and structured chapter items, figures, and sentences on atopic dermatitis in numerous medical articles, and assigned semantic information to the structured data.

We then succeeded in obtaining the information needed through a highly usable search web application. The data were obtained in a small amount of time and with a high degree of accuracy (about 90% correct/incorrect rate for similar searches by researchers).

Dolffia is highly scalable and can be tuned to handle a wide range of fields, including drug discovery. This solution can be widely used by other pharmaceutical companies for text, charts, and tables analysis.



3.1 Advancing Drug Discovery Research with AI

- **LITRON**[2]

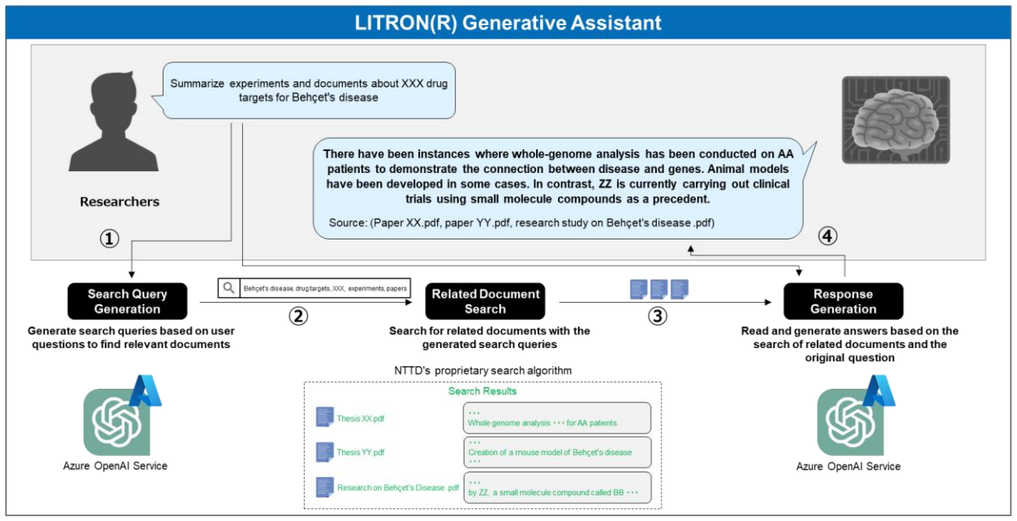
LITRON is an AI text analysis solution with specialization in industry-specific terminology and a human-like understanding of the context and meaning of information. It can structure important information from any document and build predictive and analytical AI based on the information obtained.

It can learn how to read and understand documents by interacting with experts. LITRON also crosses out the need to identify industry-specific expressions or learn vast amounts of industry documents in advance. This system can be applied to a wide range of business scenarios as it can learn industry-specific expressions and terminology more quickly than conventional methods.

So far, in pharmaceuticals, we have extracted highly accurate information from approximately 50,000 iPS cell-related papers and built an AI model that predicts the results of experiments in the field of regenerative medicine. By learning from numerous drug inserts, LITRON has also succeeded in detecting the risk of drug combinations with a higher level of accuracy than that of experts (pharmacists). LITRON is being used not only for simple data extraction but also for a variety of analytical tasks.

LITRON Generative Assistant

NTT DATA also offers the LITRON Generative Assistant, equipped with generative AI. The LITRON Generative Assistant searches for related company documents based on the question and provides not only answers to the question but also references of the text.



- **tsuzumi**[3]

tsuzumi is a lightweight large-scale language model (LLM) developed by NTT with top-level language processing performance.

Large-scale language models (LLMs) such as ChatGPT, have attracted much attention in the past, but still have processing issues. For example, LLMs have strong language processing ability, but the amount of energy needed for training them is equal to the energy consumed by a nuclear power plant in one hour (specifically in the case of GPT-3).

Additionally, the system requires a large GPU cluster for operation, and the cost of tuning and inference for various industry-specific applications is enormous, making sustainability and the financial burden of preparing a learning environment for companies an issue.

In response to these challenges, NTT Laboratories has leveraged its 40+ years of accumulated natural language processing research and world-class AI capabilities to develop tsuzumi. Although this LLM is lightweight, it has world-class Japanese language processing performance. So far, we have conducted a PoC with Kyoto University Hospital in Japan for structuring electronic medical record information.

Features of tsuzumi

- **Ultra-lightweight LLM:**

The parameter size is about 1/300 of GPT-3, which reduces the cost required for training and inference.

- **High language processing performance:**

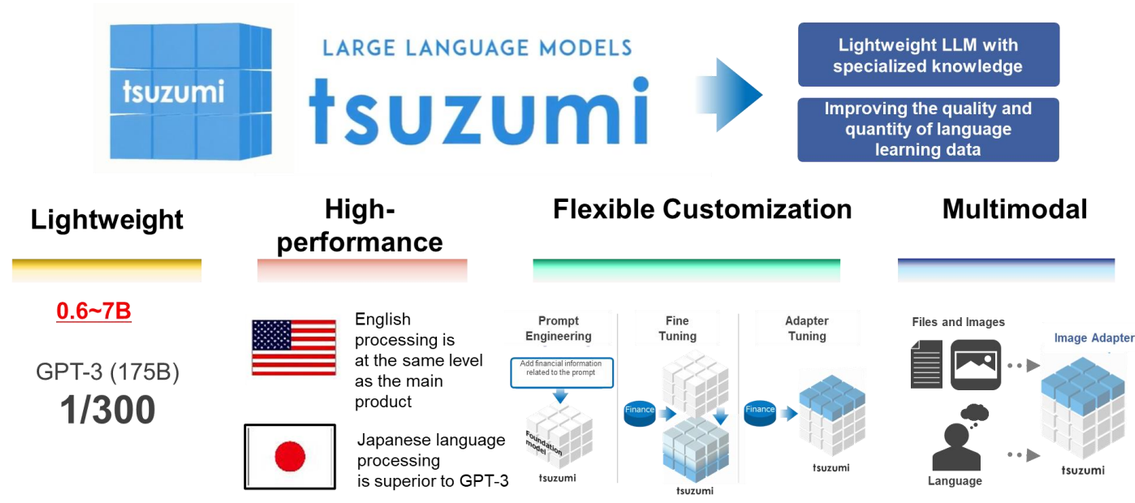
It supports both English and Japanese and has the same level of performance as other LLM products (multi-language support planned). (Multilingual support is planned).

- **Flexible Tuning:**

Adapters that enable efficient knowledge learning allow tuning for industry-specific expressions and knowledge with a small learning curve.

- **Multimodal:**

In addition to reading charts and diagrams, the system can understand non-verbal graphical representations, nuances of speech, facial expressions, etc.



3.2 Accelerating Clinical Trials: Collection and Use of Outcome Data

Collecting and Utilizing Outcome Data to Expedite Clinical Trials

In the previous section, we introduced the latest case studies on the use of sensors and AI technology to expedite clinical trials. In this section, we will discuss NTT DATA's solutions for gathering patient information and outcome data. We will also look at how outcome data is being used to expedite clinical trials.

Challenges in Utilizing Outcome Data

The integration of eSource data, which refers to electronically recorded information, such as electronic medical records, with Electronic Data Capture (electronic collection of clinical laboratory information: EDC), has garnered interest as a means to enhance the effectiveness and quality of clinical trials. The importance of this approach has become common knowledge throughout the industry. However, there are challenges that need to be addressed before it can be fully adopted.

One specific issue is that there are many types of electronic medical record products for medical institutions and EDC products for study sponsors, and the specifications are not standardized. In many cases, data exported from electronic medical records cannot be imported into EDC without modification. As a result, time-consuming adjustments and handling are required to transfer data between electronic medical records and EDC, and data linkage is stagnant.

- **PhambieLINQ**[1]

PhambieLINQ, a comprehensive clinical trial platform, has been developed to address data transfer and linkage concerns. PhambieLINQ standardizes data output from various eSource data systems and links them to various electronic clinical data capture (EDC) systems. As a comprehensive cross-industry clinical trial platform, PhambieLINQ enables the collection and linkage of eSource data through the two following functions:

① Support clinical data collection at medical institutions, etc.

② Linkage of clinical data from medical institutions to study sponsors

PhambieLINQ Features

- **Connection to Electronic Medical Record System:**

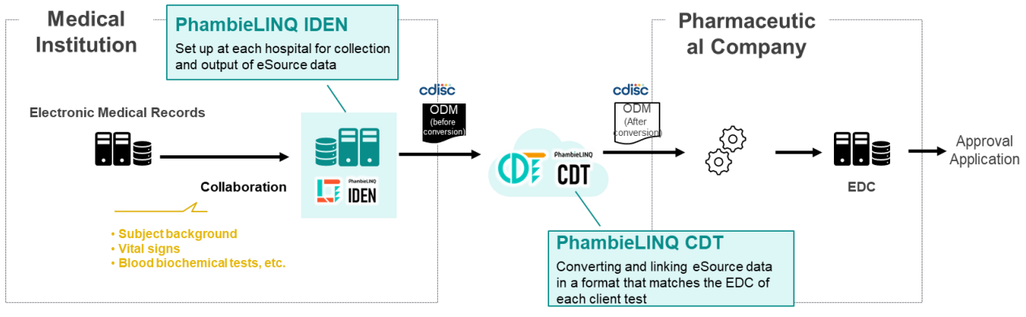
The required details from source documents, which are stored in the electronic medical record system, are electronically connected to the study sponsor through a case report. PhambieLINQ reduces the labor involved in Source Document Verification (SDV) (direct viewing).

- **Multi-vendor Support:**

It is compatible with a variety of electronic medical record systems and EDC systems and can be used for any type of examination.

- **Development from a Medical Institution Perspective:**

The system is user-friendly for medical institutions, with the addition of an experienced Clinical Research Coordinator (CRC) to the development team. Our dedicated team is also available for introduction support and user training for operation.



- **Outcome Data Case Studies**[2][3][4]:

AI model to determine drug treatment efficacy for RWE creation:

In addition to collection and linkage of outcome data, NTT DATA is co-creating solutions based on the use of outcome data with pharmaceutical companies.

In 2023, in collaboration with Miyazaki University and Pfizer, we built an AI model to determine the effectiveness of drug treatment for lung cancer patients based on their electronic medical records. This model extracts drug treatment effects from electronic medical records through natural language processing of unstructured data.

In this joint research, NTT DATA built BERT, an LLM based on the electronic medical record data of Miyazaki University. Our goal was to establish Real World Evidence (RWE) using fast and extensive data, while also confirming its suitability and effectiveness with electronic medical records from six medical institutions.

As a result of this study, we confirmed that we can construct an AI model to determine drug treatment efficacy that can be applied to electronic medical record data from multiple medical institutions. We also confirmed that the TTPs extracted by the model showed the same trends as those extracted by humans.

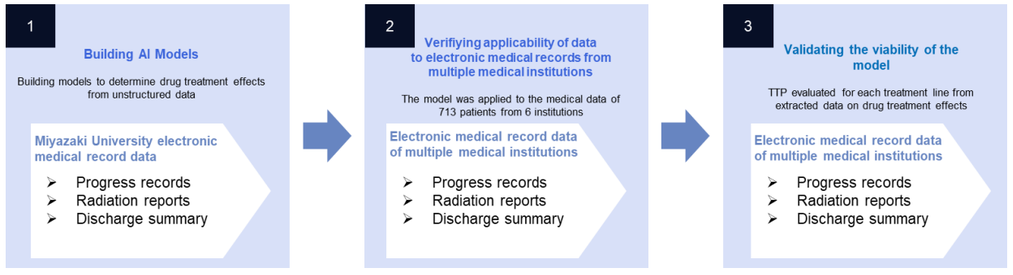
The use of unstructured data and the creation of RWE are expected to expand further. They can be applied to compare treatment effects among drugs and determine drug treatment effects for diseases other than lung cancer.

Research Details

Step 1: Created training data from electronic medical records of 31 lung cancer patients who attended or were hospitalized at the University of Miyazaki Hospital. Physicians evaluated the training data, and we examined the method of constructing a model for judging the effectiveness of drug treatment using BERT. We applied a domain-specific BERT construction framework to perform pre-training, constructed a model specialized for cancer treatment, and then conducted fine-tuning.

Step 2: Applied the constructed model to the electronic medical record data of 713 lung cancer patients from 6 medical institutions obtained based on the Next Generation Medical Infrastructure Act and verified its applicability.

Step 3: Evaluated TTP, an endpoint used in clinical research, from the extracted drug treatment effects. The results extracted by humans and those estimated by the model were compared and evaluated, and the viability of this method was confirmed.



3.3 Establishing an Efficient Supply Chain

Challenges in Achieving an Efficient Supply Chain

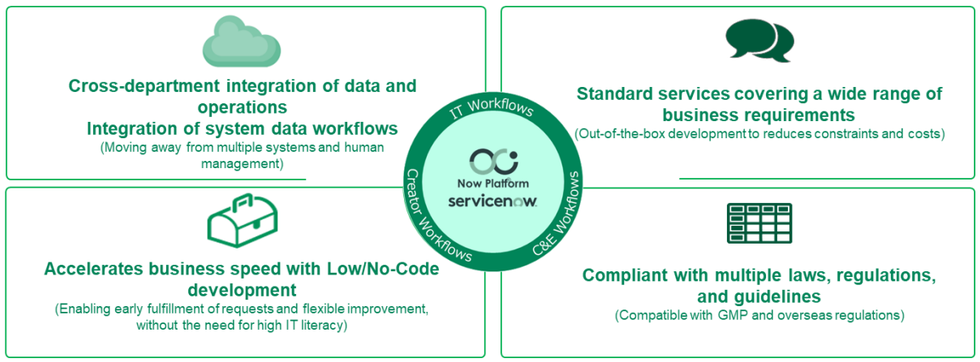
In patient-centered medicine, the prompt delivery of medicines to patients is a high-priority issue. To achieve this, a flexible and fully optimized process from production to distribution (one-to-one supply chain) is required. An efficient supply chain includes optimization of the production system and providing traceability. This section introduces NTT DATA's initiatives with a focus on ServiceNow as a solution that contributes to the overall optimization of the supply chain.

- **ServiceNow**

ServiceNow is a cloud-based platform and solution by ServiceNow, Inc. It augments digital workflows to create a superior experience and increases productivity for both employees and the enterprise. The platform can be used to integrate systems and data across multiple departments and operations. The solution is used in a wide range of industries, not limited to the pharmaceutical industry. However, it is compliant with various regulations specific to the pharmaceutical industry, and it enables business efficiency while guaranteeing a high level of security.

NTT DATA has a wealth of ServiceNow-based solutions, including those used by Novavax to streamline its internal operations[1]. These solutions help pharmaceutical companies achieve greater operational efficiency.

NTT DATA's systems for **investigational new drug management**, **outbound shipment judgment & quality review**, **post-marketing surveillance (EPPV)/adverse reaction reporting**, and **adverse event reporting management** have made significant contributions to improving the efficiency of clinical trials, production management, distribution, and sales.



- **Solution 1: Clinical Trial Drug Management System**[2]

NTT DATA and Chugai Pharmaceutical

Considering recent changes in Japan's Good Clinical Practice (GCP), a sponsor's obligation to report adverse drug reactions has expanded from investigational drugs to investigational drugs (other companies' products/commercial products).

In response to this amendment, Chugai Pharmaceutical, which conducts multiple clinical trials, has named several investigational drugs, including commercial products of other companies, as subject to mandatory reporting in each clinical trial.

Under these circumstances, there could be an overflow of human resources and person-hours, leading to problems in the management of investigational new drugs. NTT DATA applied its investigational drug management system, which efficiently manages investigational drug information and avoids non-compliance in safety information management.

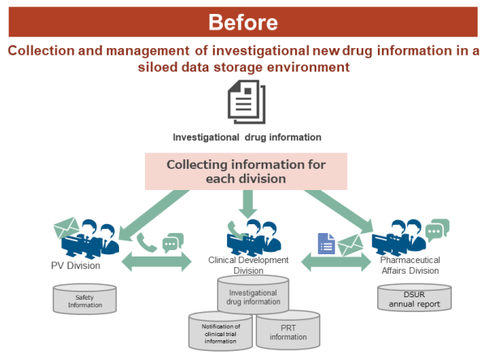
Solution Implementation Effectiveness

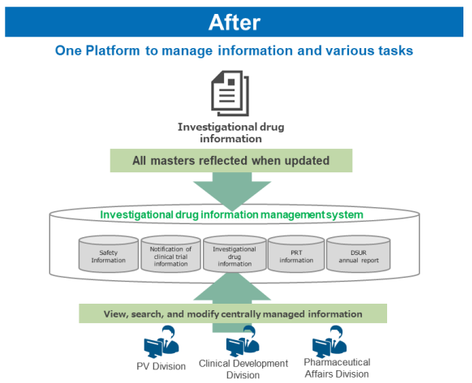
- Centralized management of basic information on investigational drugs used in all clinical trials.
- Easy search and retrieval of up-to-date information when needed by the person in charge.
- Timely sharing of updated information to relevant parties.
- Audit trail/change history function to check the transition of information.

***Glossary:**

Good Clinical Practice (GCP)

GCP is a set of standards to be followed when conducting clinical trials. It is required by law to protect the human rights and safety of subjects and to protect the scientific integrity of clinical trial data.





3.3 Establishing an Efficient Supply Chain

- **Solution 2: Shipping Judgment and Quality Verification System**[3]

NTT DATA and Otsuka Pharmaceutical

Pharmaceutical companies guarantee quality, efficacy, and safety of pharmaceutical products to provide better medicines and products to medical institutions and patients. To this end, the Quality Assurance Department reviews manufacturing/testing records and makes sure that deviations that occur during these processes are properly handled. The quality team decides whether to ship the drugs after assuring quality from various perspectives.

Quality verification is an indispensable process for shipping safe and reliable products to the market.

Manufacturing records and quality test records are checked against dozens of parameters as well as results from the perspective of data reliability assurance. It is also mandatory to investigate any deviation/change controls that affect the products to be shipped and confirm if it has been handled appropriately.

Japan's Good Manufacturing Practice (GMP) ordinance was amended in 2021. The changes mandate higher levels of management responsibility, quality assurance department operations, control of shipments from manufacturing facilities, data integrity, and change control/deviation control. Against this backdrop, there is an increasing complexity and need for a higher level of management intervention under the revised GMP.

NTT DATA and Otsuka Pharmaceutical developed a solution to reduce the manual workload of shipping judgment to achieve a higher level of quality assurance.

Solution Overview and Implementation Benefits

The solution links multiple IT systems within the company and centrally manages manufacturing records and quality test verification results. The data also covers lots of products to be determined for shipment, as well as quality information such as deviation/change management.

This platform improves the certainty of verification work in shipment judgment operations and streamlines the information collected through centralized management. The necessary information can be immediately retrieved and viewed. All personnel involved in the shipment judgment can access the same platform, allowing seamless coordination of information between operations across divisions.

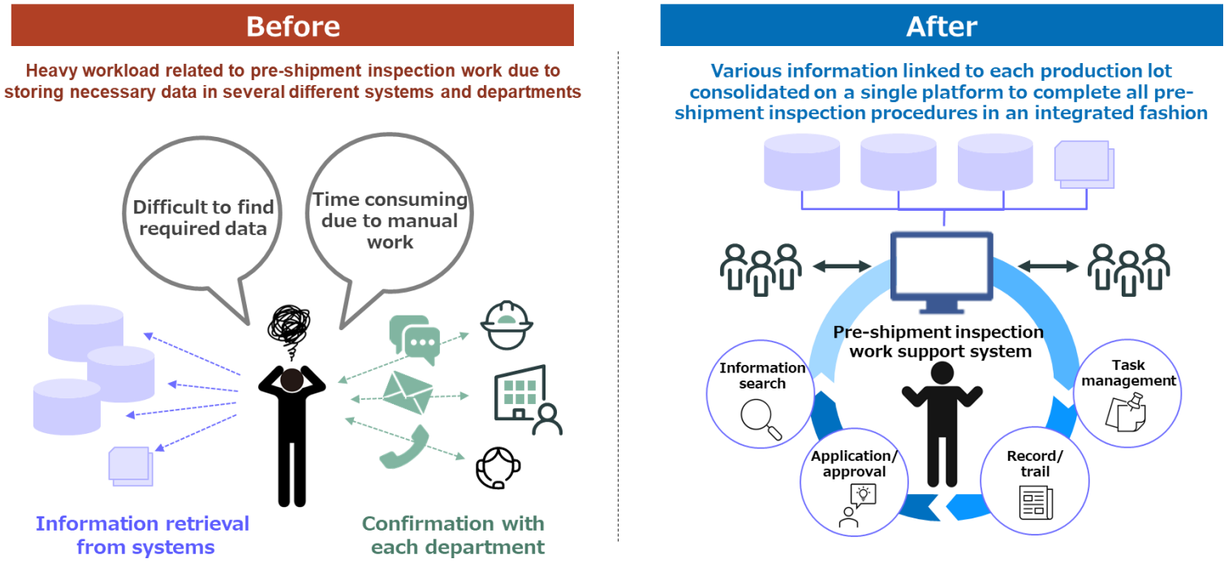
The system also enables the consolidation of information on products to be shipped, making it possible to perform all operations at one place. This led to improved transparency in the manufacturing process and contributed to the deterrence of human error.

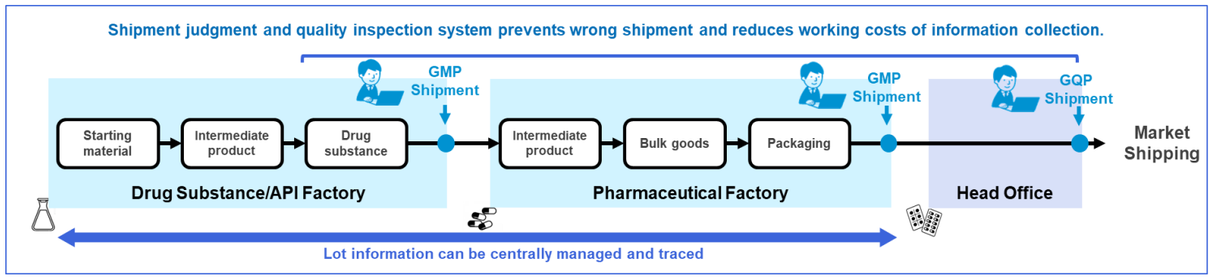
Otsuka Pharmaceutical introduced this system at all six of its pharmaceutical manufacturing plants in Japan. The company began full-scale operations in April 2023 for product-related shipment judgment operations.

***Glossary:**

Good Manufacturing Practice (GMP)

GMP is a manufacturing and quality control standard for pharmaceuticals. It establishes three principles: minimizing human error, preventing contamination and quality deterioration of pharmaceuticals; and designing systems to ensure high quality.





3.3 Establishing an Efficient Supply Chain

- **Solution 3: Post-marketing Surveillance/Adverse Reaction Reports**

NTT DATA and Takeda Pharmaceutical Company

Under Japanese GVP regulations, once a drug is launched, post-marketing surveillance activities are necessary. The following challenges are prevalent in post-marketing surveillance and adverse reaction reporting:

- Lack of medical resources.
- Pressure on pharmaceutical companies to manage post-marketing surveillance while also conducting sales activities.
- High pharmacovigilance workload due to the vast number of post-marketing surveillance situations and report approvals.

Furthermore, post-marketing surveillance and adverse reaction reports are subject to the accurate understanding of physician reports by the MRs in charge. This personalized task depends on the experience of the MRs, and the level of standardization that was sought.

In response to these issues, NTT DATA deployed a ServiceNow-powered online system to manage post-marketing surveillance and adverse reaction reporting in a single system.

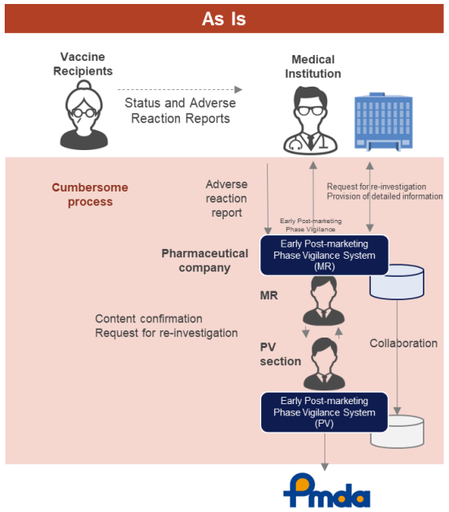
Solution Overview and Implementation Benefits

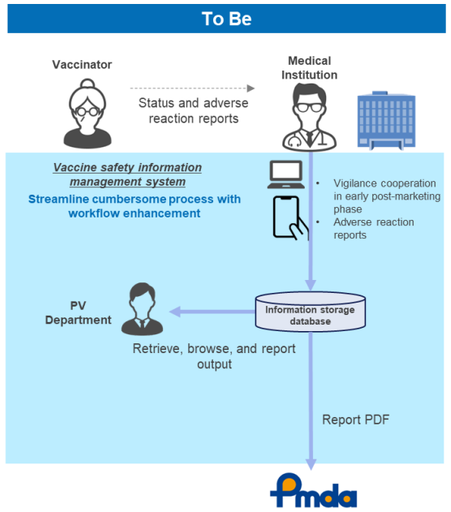
This solution has enabled a complete shift from paper-based post-marketing surveillance and adverse reaction reporting to the web (mobile-enabled) in Takeda Pharmaceutical Company. Most of the MR visit correspondence and activity records are now documented through email distribution and access log aggregation.

***Glossary:**

Good Vigilance Practice (GVP)

Good Vigilance Practice is a regulation that stipulates post-marketing safety management of pharmaceuticals and other products.





- **Solution 4: Adverse Event Reporting Management System**

Background

The COVID-19 pandemic led to restrictions on visits to medical institutions in Japan, resulting in a decrease in the number of medical representatives (MRs) for pharmaceutical companies. This has also created more opportunities for obtaining drug information digitally, through remote interviews and web lectures. Furthermore, healthcare professionals who provide information on drug prescriptions are facing an increasing need to reform their work styles, triggered by increasing workloads.

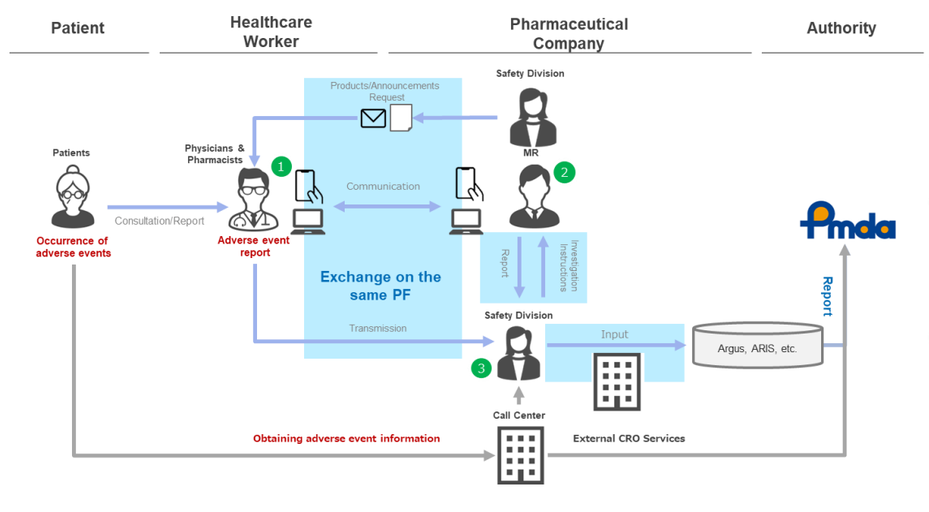
Pharmaceutical companies and healthcare professionals are required to continue using digital technology to collect and provide prompt and high-quality medical information to improve efficiency.

The collection and provision of medical information involves reporting of adverse events by patients and healthcare professionals to pharmaceutical companies and authorities. This process is currently done in person and on paper, which creates a burden on the workflow. NTT DATA has developed an adverse event reporting management system using ServiceNow to enhance the reporting workflows.

Solution Overview and Implementation Benefits

This solution streamlines the collection of traditional MR visit-based information for physicians and pharmacists, allowing for easier completion on ServiceNow. Reporting from MRs to pharmacovigilance departments and linkage to safety management information databases (Argus, ARIS) can also be handled on ServiceNow.

The reporting system has enabled healthcare professionals to reduce their workload and respond to patients more quickly. Pharmaceutical companies have also realized efficient MR activities and efficient information collection in the pharmacovigilance department.



3.4 Common Value Chain Solutions

Common Value Chain Solutions

Solutions that cater to the entire pharmaceutical value chain are essential to improve operational efficiency and create value at every stage, including research, clinical trials, manufacturing, and distribution.

This section delves into digital platforms that address the unique constraints of the pharmaceutical industry. We will introduce medical information platform **Millennium Medical Records** and **GxP Data Lake**, a data utilization platform.

Millennium Medical Records[1]

Millennium Medical Records is a medical information platform aimed at providing optimal medical care to patients. The platform is jointly operated by the Life Data Initiative (LDI) and NTT DATA. It handles RWDs such as receipt data, DPC data, and electronic medical record data.

The Millennium Medical Records is linked to and stores various RWD from hospitals and clinics in the **EHR Center**. The Japan Medical Network Association, a non-profit organization; LDI and NTT DATA perform anonymization of the data stored in the EHR Center in accordance with applications from users (pharmaceutical companies, medical institutions, academic organizations, etc.). The data is provided after name identification, anonymous processing, etc. of the data.

It is possible to evaluate treatment outcome results precisely by linking electronic medical record text information and laboratory value information with receipts and DPC data. NTT DATA has presented its results at various medical technology and clinical conferences.

In the PHR business, NTT DATA is working to achieve data-driven enhancements of MX. We are linking **digital phenotypes** and **digital biomarkers** transmitted by patients using applications that we are jointly developing with PSP to EHR systems.

Detailed information (as of December 31, 2023)

- **Participating Facilities**

University and public hospitals.

- **Number of Participating Facilities**

54 facilities *Notification has been submitted to the approval authority (Cabinet Office).

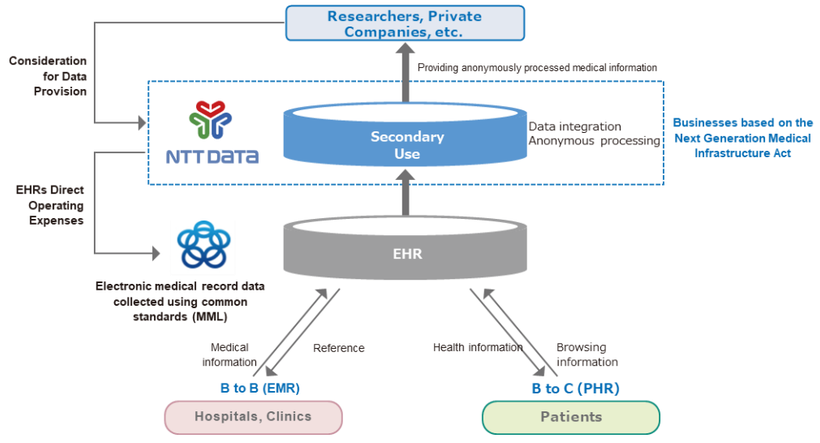
- **Number of registered patients**

1.79 million *Number of patients registered for secondary available data.

- **Typical examples of utilization**

Ono: Determination of medication efficacy for patients with inflammatory bowel disease[2].

Pfizer: Construction of an AI model to determine the effectiveness of drug therapy[3].



- **GxP Data Lake**[4]

NTT DATA has extensive knowledge in developing data utilization platforms (GxP Data Lake) that meet the strict system development standards of the pharmaceutical industry.

Pharmaceutical companies require a mix of IT systems for manufacturing, clinical trial management, quality control, customer management, and systems specialized for pharmacovigilance.

Systems related to pharmaceutical manufacturing present challenges in data management. For example, from an auditing perspective, data integrity must comply with regulations set by authorities in each country. Efficient utilization of data while preventing siloing in each value chain is crucial to providing high-quality pharmaceutical products that give pharmaceutical companies an advantage. GxP Data Lake addresses these data utilization challenges.

NTT DATA has supported several major pharmaceutical companies in the U.S, Germany and Japan.

GxP Data Lake Features:

- **Responds to Diverse Analysis Needs**

Conventional data warehouses store only data that has been optimized for a defined purpose. This makes it difficult to conduct analysis trials that meet the flexible needs of users. On the other hand, a data lake can meet the flexible needs of data users by storing data with no defined purpose of use.

- **Supports a Variety of Data Formats**

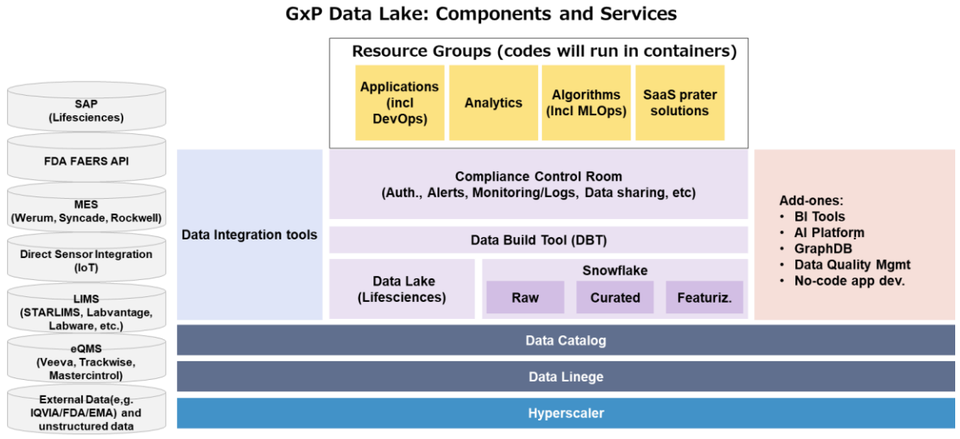
It supports not only structured data such as purchasing data and CRM, but also unstructured data such as text, video, and audio.

- **Protect Data Integrity**

Protecting data integrity involves preserving collected data in its original format and retaining both data conversion details and original data information while processing the data. By storing data for pharmaceutical manufacturing and other purposes, it is possible to comply with regulations in various countries.

- **Linkage with a Variety of Analytical Tools**

It can be linked to a wide range of analysis tools such as BI/AI, enabling data analysis according to business characteristics and user competence.



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