Background to Growth Strategy Development

Previous Mid-Term Business Plans

2008 2009 2010 2011 2012 | 2013 2014 2015 | 2016 2017 2018 | 2019 2020[8]

Sunrise 2012

Formulation and launch of the "top pharmaceutical company" goal[1]

Business environment

- Emphasis on unmet medical need
- Stronger pressure to contain healthcare costs

Strategies

- Strengthen portfolio management
- Exhibit strategic marketing functions
- Maximize company-wide productivity

Results and issues

- Established high profitability
- Continuous stream of in-house candidates into clinical development
- Developed and established recycling antibody engineering technology and other proprietary antibody engineering technologies
- Promoted personalized healthcare (PHC)

Quantitative guidance

	Sales (Billions of yen)	Operating profit (Billions of yen)	Operating profit margin (%)
2012 targets	460.0	80.0	17.4
Results	391.2	76.4	19.5

ACCEL 15

Prepare the foundation for achieving the "top pharmaceutical company" goal

Business environment

- Evolution of discovery technology
- Stricter drug approval requirements
- More severe impact from drug price revisions

Strategies

- Increase marketing productivity
- Accelerate global development
- Continuously generate innovative projects
- Further strengthen management infrastructure

Results and issues

- Product growth exceeding market average
- Advances in global development of in-house products including Alecensa
- Strengthened R&D structure with expansion of CPR,[2] establishment of TCR Division,[3] etc.
- Enhanced functions for providing solutions

Quantitative guidance

	Core EPS[4] CAGR[5]
3-year target (2012–2015)	Mid to high single digit[6]
Results	18.3%

IBI 18

Realization of the "top pharmaceutical company" goal

Business environment

- Advances in life science
- Increasing difficulty of creating new drugs
- Fierce global competition

Strategies

- Acquisition and implementation of competitiveness at a top global level
- Selection and concentration strategy for acceleration of growth (Set 13 priority issues in 5 areas: Drug discovery, development, pharmaceutical technology, marketing & sales/medical affairs/drug safety, and Company-wide)

Results and issues

- Achieved record-high results
- Continuously created therapeutic antibody projects and enhanced the mid-size molecule drug creation technology platform
- Prepared for approval and accelerated growth of Hemlibra and Tecentriq
- Created a structure for providing solutions by region

Quantitative guidance

	Core EPS CAGR
3-year target (2015–2018)	Low single digit
Results	17.1%[7]

IBI 21

Creating shared value through innovation

Business environment

- Increased demands to reduce drug prices
- More competitive environment including generics
- Further advances in life science technologies

Strategies

Create global growth drivers and maximize value, and strengthen HR and infrastructure that support Chugai's business through the following five strategies: Value creation, value delivery, promote advances in PHC, strengthen human capital and fundamental structural reform, and strengthen sustainable platforms.

Results and issues

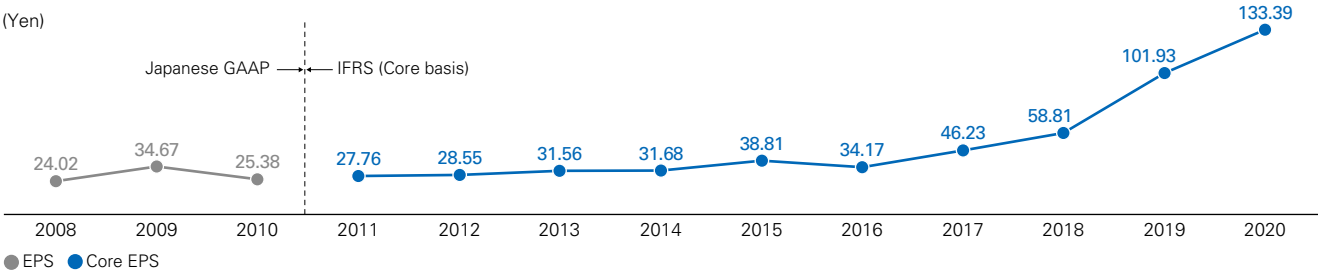
- Achieved record-high results
- Global growth of products from Chugai research, domestic growth of new products
- Steady progress with in-house drug discovery themes, including next-generation antibodies and mid-size molecules
- Progress with in-house drug discovery projects, including launch of Enspryng as a next-generation growth driver
- Enhanced foundation for growth, including introduction of new HR system and development of digital infrastructure

Quantitative guidance

	Core EPS CAGR
3-year target (2018–2021)	Around 30%[9]
Results (2018–2020)	49.5%

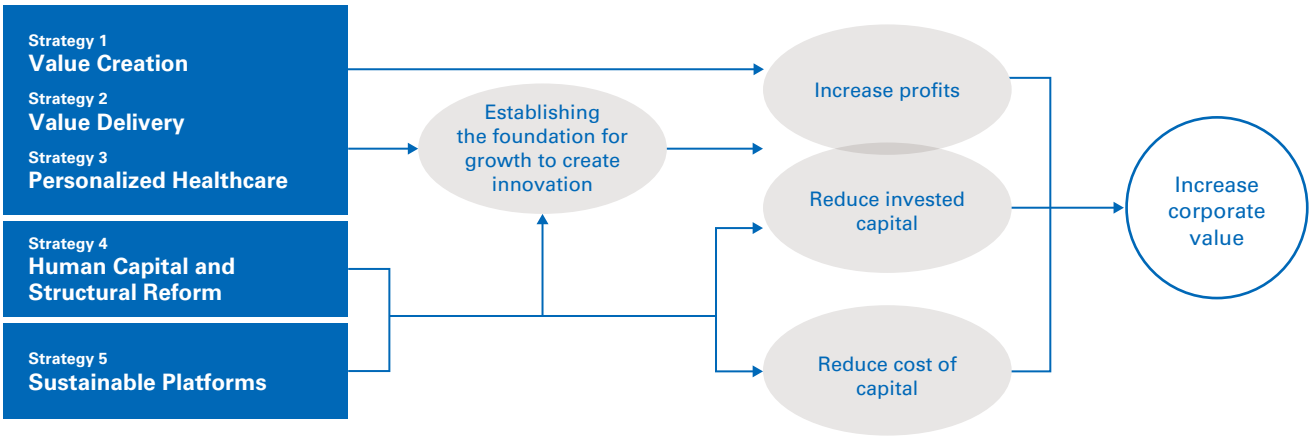
1. A vision for Chugai to be realized in the second half of the 2010s. It sets numerical targets including ranking within the top three major Japanese pharmaceutical companies, the No. 1 domestic presence in our strategic disease areas, and expansion of global presence, and qualitative targets including becoming a company that receives the support and trust of all stakeholders and conducts independent activities.
2. Chugai Pharmabody Research Pte. Ltd. Established in Singapore in 2012.
3. Translational Clinical Research Division. Partially reorganized into the Translational Research Division in October 2018.
4. Diluted earnings per share attributable to Chugai shareholders on a Core basis 5. Compound annual growth rate 6. Based on average exchange rates for 2012
7. Based on average exchange rates for 2015 8. Completed one year ahead of schedule
9. Based on average exchange rates for 2018. Does not take into account the stock split during the year.

EPS / Core EPS[10]



10. Effective July 1, 2020, Chugai has implemented a three-for-one stock split of its common stock. Calculated based on the assumption that the stock split was implemented at the beginning of 2008.

IBI 21 Review



All of Chugai's strategic initiatives feed into increasing corporate value over the medium and long term. The various strategies in IBI 21 were all strategically designed and managed to produce the outcomes listed above, namely establishing the foundation for growth to create innovation, increasing profits, reducing invested capital, and lowering cost of capital. The chart below provides a review of IBI 21, summarizing each strategy from the perspective of the impact it has on increasing corporate value.

Strategies	Summary	Contribution to higher corporate value
Strategy 1 Value Creation	**Steady progress in drug discovery, including progress of in-house projects** • Mid-size molecule project: Progressed as planned toward phase I launch in 2021 • Antibody project: Phase I started for next-generation switch antibody-STA551 • Launch of global phase III for crovalimab/SKY59, approval of Enspryng and start of sales	• Innovation that drives future profit growth • Establish a foundation to create innovation in science and technology
Strategy 2 Value Delivery	**Expand market penetration of growth drivers and accelerate value maximization** • Hemlibra: Significant increase in overseas revenues and expanded the number of countries with approval • Tecentriq: Progress in expanding indications including first in class (FIC)	• Maximize product value to grow medium- and long-term profits
Strategy 3 Promote Advances in Personalized Healthcare	**Formulation of CHUGAI DIGITAL VISION 2030 and promotion of cancer genomic medicine** • Digital: Progress of company-wide digital strategy and acceleration of AI drug discovery, etc. • Launch of FoundationOne CDx and approval of additional indications, approval filing for FoundationOne Liquid CDx • Filing for ROS1 indication of Rozlytrek using RWD as reference data	• Improve capital efficiency, productivity • Reduce future costs for digital applications and new modalities
Strategy 4 Strengthen Human Capital and Conduct Fundamental Structural Reform	**Progress in transforming systems to support innovation** • Started operation of a new HR system • Progress with structural reforms in corporate and prioritized divisions	• Build corporate culture that fosters innovation • Recruit and develop diverse, high-caliber talent • Improve productivity
Strategy 5 Strengthen Sustainable Platforms	**Enhancing platforms to support efforts for innovation** • Selected to DJSI World for the first time • Enhanced stakeholder communication	• Reduce EHS and supply chain risk • Reduce quality and reliability risk • Understand society's expectations and requirements

New Growth Strategy TOP I 2030

Global First-Class Drug Discovery

- Expansion of existing technological bases and building a new technological foundation to materialize unique drug discovery ideas
- Launch in-house global products every year by doubling R&D output
- Acceleration of innovation opportunities by leveraging digital technologies and strengthening collaboration with leading global players

Futuristic Business Model

- Dramatic improvement in product/patient value by restructuring business model, having digital utilization as a core
- Improve productivity of entire value chain by leveraging digital technologies
- Commercialization of Insight Business with the aim of maximizing the value of pharmaceuticals and having a new business pillar

Key Drivers • DX • RED* Shift • Open Innovation

* RED: Research & Early Development

Overview of TOP I 2030

Summary of Strategy

The new growth strategy TOP I 2030* is based on two pillars—global first-class drug discovery and a futuristic business model—and we have defined three key drivers and five reforms to achieve this strategy. Our targets for 2030 are to double R&D output and become a company that can launch innovative in-house global products every year.

* TOP expresses our aspiration to become "the world's top innovator, not just in Japan." The "I" has two meanings: in addition to "innovator," it also expresses that each and every member of the Chugai Group plays an important role in our efforts to realize TOP I 2030.

Two Pillars to the Strategy

To achieve global first-class drug discovery, we will expand our existing technological bases and establish a new technological foundation. At the same time, we will build a futuristic business model that takes into account environmental changes and technological advances. We will fundamentally rebuild our value creation model with the goal of achieving a dramatic increase in productivity across the entire value chain and delivering greater value to patients.

Three Key Drivers

Under RED Shift, we will focus the investment of business resources in the processes involved from drug discovery through early development in order to create a continuous cycle of innovation in the future. Under digital transformation (DX), we will enhance our digital infrastructure and improve productivity across all value chains, with the goal of utilizing digital applications for innovative new drug discovery. Under open innovation, we will step up collaborations with external partners, focus on the application of external technologies, take a flexible approach to the adoption of new advances in science and technology, and work to create new opportunities for innovation.

Policy on Shareholder Returns

Our policy on shareholder returns is to aim for a dividend payout ratio of 45 percent on average based on Core EPS to provide stable dividends, taking into account the balance between shareholder returns and the internal reserves necessary for increasing corporate value.

Five Reforms

1. Drug Discovery

- Expansion of existing technological bases and building a new technological foundation to materialize unique drug discovery ideas
- Acceleration of innovation opportunities by leveraging digital technologies and strengthening collaboration with leading global players

2. Development

- Early maximization of product value through advanced human prediction and simultaneous drug development for multiple diseases
- Realization of advanced and efficient clinical development operations using digital technologies

3. Pharmaceutical Technology

- Establishment of competitive mid-size molecule production technology
- Establishment of world-class antibody drug manufacturing technology and acceleration of development
- Set up efficient production systems by utilizing digital and external resources

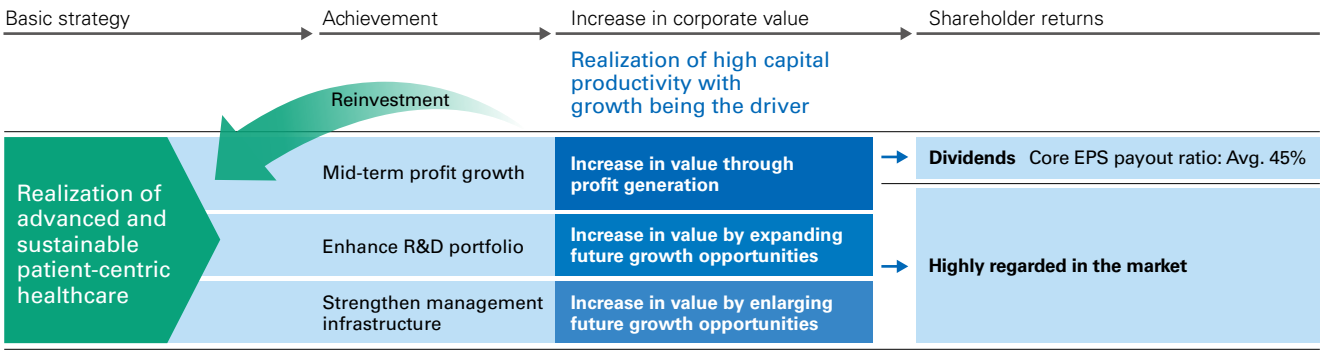
4. Value Delivery

- Maximize customer value by innovative digital-based customer engagement model
- Realization of further personalized medical care by the creation of unique evidence

5. Foundation for Growth

- Acquisition of the talent and the establishment of an organizational structure / HR system to support creation of innovation
- Realization of CHUGAI DIGITAL VISION 2030
- Quality management that achieves both quality and efficiency
- Conduct global environment measures
- Pursue opportunities of Insight Business

Basic Principles of Increasing Corporate Value and Shareholder Returns



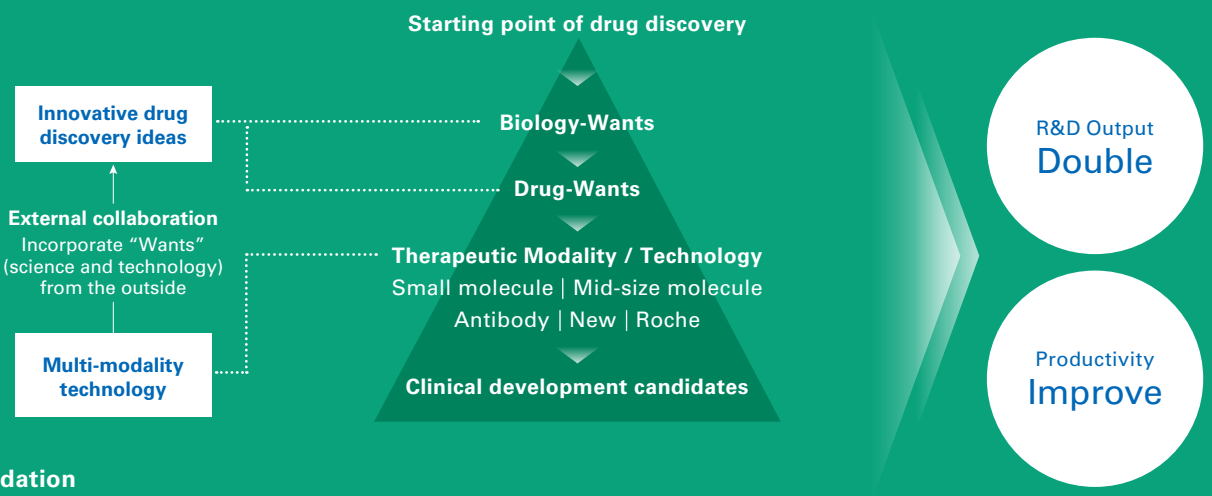
Direction in 2021

Maximizing value of growth drivers	• Accelerate market penetration by mainstay products, successful launch of new products • Distribution system reform
Continuous creation of R&D output	• Steady achievement of plans for submissions and approvals • Convert in-house post-proof of concept (PoC) projects into growth drivers, demonstrate value of in-house pre-PoC projects • Start phase I clinical trials and expansion of mid-size molecule projects • Continuous creation of drug discovery projects
Acceleration of DX	• Accelerate DX across the entire value chain (AI drug discovery, clinical predictability, clinical/pharmaceutical operations, customer engagement models, DX infrastructure)
Strengthen business foundation	• Strengthen business foundation to support creation of innovation (HR management, Insight Business, ESG, structural reforms)

1. Drug Discovery

To realize innovative drug discovery ideas, we aim to double output by strengthening digital capabilities, promoting external collaboration, and enhancing our drug discovery technology platforms.

Multi-modality drug discovery



Foundation

AI-based drug discovery, next-generation lab automation, Chugai Life Science Park Yokohama

Global First-Class Drug Discovery

Chugai has created many innovative new drugs thus far by leveraging the Company's unique capabilities in science and technology. In TOP I 2030, we will build on the strengths of our in-house drug discovery capabilities accumulated over the years, while further enhancing our drug discovery technology platforms to realize creative drug ideas.

Multi-Modality Drug Discovery

Chugai's proprietary small molecule and antibody technologies have successfully expanded our technology base. We continue to accelerate drug discovery using our unique technologies, including switch antibody technology, and are focusing on further technology developments. As for mid-size molecules, our third modality, the first project is scheduled to enter clinical trials during 2021. We expect this modality to become a main pillar of medium- to long-term growth, and will prioritize the allocation of business resources to technology development and clinical projects in this field. Mid-size molecule drugs can reach targets that were previously difficult to access, and have high binding activity, and good oral absorption. We hope this will enable us to solve unmet medical needs that cannot be addressed with conventional modalities.

In addition, we are leveraging our expertise in protein engineering technologies to establish new modalities. We will pursue a multi-modality strategy by flexibly incorporating external science and technology as necessary, identifying "Drug-Wants" (profiles and mechanisms of action wanted in drug discovery) not achievable with conventional technologies, and creating platforms as a means to solve them. In addition to stepping up our collaborations with Roche and the Immunology Frontier Research Center (IFReC) at Osaka University, Chugai will actively collaborate with external parties who have new technologies or knowledge in order to accelerate technology development and explore potential modalities.

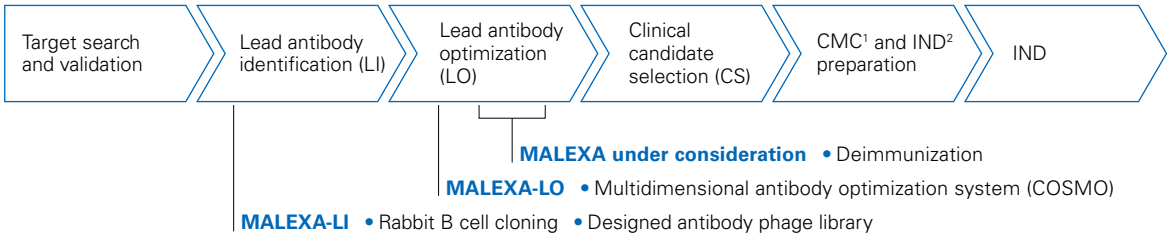
Reinforcing Drug Discovery Platforms

The application of digital technologies, including AI drug discovery, is essential to advance drug discovery technology and transform the drug discovery process. We are already working to utilize AI in our antibody discovery platforms, and to improve the efficiency of our drug discovery process using digital technology. We plan to expand and accelerate these initiatives going forward. Focus will also be placed on a smooth transition to Chugai Life Science Park Yokohama, which is scheduled to officially start operations in 2023, and on next-generation laboratory automation.

Case Studies

Innovating Drug Discovery Processes Using AI

In the field of drug discovery, we are using AI to transform various processes. For example, in the creation of antibody drugs, we are promoting an initiative called AI Machine Learning x Antibody (MALEXA) to select therapeutic antibodies for drug discovery purposes. By learning the patterns of a large number of antibody amino acid sequences during the selection process, we are able to propose candidate sequences in a short timeframe. Antibodies with strong binding activity have already been successfully obtained in a number of projects. For antibody optimization as well, we have confirmed that machine learning can be used for sequence generation and predictive modeling, which allows us to propose antibody sequence groups based on optimal pharmaceutical characteristics, including binding activity, pH dependency, and physical properties. Currently, we are investigating the application of this technology to reduce immunogenicity, and have started to apply AI technologies in mid-size molecule drug discovery platforms as well. In addition, through a collaboration with FRONTEO, Inc., we are using AI-based text mining technology to vectorize 16 million published papers and build a system that can extract information from multiple sources. The goal is to achieve greater efficiencies in research processes and the prediction of disease-related genes.



1. Chemistry, manufacturing, and control 2. Investigational new drug

Evolution of Antibody Engineering Technologies: Progress in Switch Antibodies

Chugai is continuously developing proprietary antibody engineering technologies, and currently we are working on a number of drug discovery projects using these novel technologies. One major development in 2020 was the entry of STA551, which uses our switch antibody technology (Switch-Ig®), into the pipeline. Conventional antibodies bind to target antigens in normal tissues as well as at sites of disease, resulting in side effects. Our switch antibody technology is expected to solve this issue by increasing the specificity of antibodies to the sites of disease. STA551, which applies this technology, is designed to only bind to CD137, the target antigen, and activate T cells in the presence of the small molecule adenosine triphosphate (ATP) (switch molecule), whose extracellular concentration increases in cancer tissues. When ATP concentrations are low, STA551 does not bind to the antigen and does not activate T cells. Conventional CD137 antibodies produced liver toxicity and other serious side effects, and it was difficult to target CD137 as the antigen of the therapeutic antibody. The application of the switch antibody technology is expected to resolve these safety issues and produce good efficacy.

	Drug discovery	Preclinical	Clinical	Launched
Recycling antibody®, Sweeping antibody® Others	2	3	• Nemolizumab • Crovalimab • AMY109 • GYM329 / RG6237	• Enspryng
Bispecific antibodies (1st, 2nd, and 3rd generation)	6	2	• ERY974 • NXT007	• Hemlibra
Switch antibody	5		• STA551	
Antibodies applying other new technologies	2			

Note: Numbers indicated at the drug discovery and preclinical stages show the number of projects.

2. Development

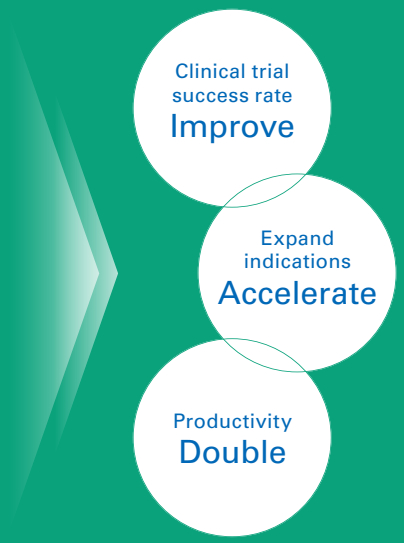
Leveraging digital technology to realize a world-class clinical development model that can improve success rates and maximize product value

Early-stage development

Improvement of success rate	• Improvement of predictability in humans through intricate understanding of biological responses and utilization of innovative technologies such as modeling & simulation (M&S) and human organoid construction
Maximizing product value	• Early demonstration of QoL/True Endpoint • Simultaneous development for multiple indications by early identification of candidate diseases

Late-stage development

Transformation of operational model	• Improve efficiency of monitoring/management tasks by using digital technologies



Early-Stage Clinical Development

Early-stage clinical development up to proof of concept (PoC)[1] is a component of the value creation engine, one of the TOP I 2030 investment priorities as part of the Research and Early Development (RED) function. Here, the key issues are to improve success rates and maximize product value in order to double R&D output. Specifically, from the preclinical stages, we are working to develop an intricate understanding of biological responses utilizing innovative technologies such as M&S[2] and human organoid construction.[3] These will be combined with the full use of real-world data (RWD) and a wealth of data on diseases and treatments that we have accumulated to improve the predictability of dosage and administration, efficacy, and safety, and to increase the success rates of clinical trials.

In the past, additional indications were developed in stages, but by using M&S and other scientific evidence, we now aim to identify target diseases at an early point and develop indications for multiple diseases simultaneously. Combining this with an understanding and analysis of biological responses, we will focus on the development of digital biomarkers (dBMs) and digital devices while identifying healthcare issues for each disease and linking the results from this work to appropriate diagnosis and treatment. Furthermore, by combining the data obtained in this way with RWD, we will demonstrate the True Endpoints that can help to improve patient QoL at the early stages, thereby maximizing the value delivered to patients.

1. Proof of concept: Confirmation that the therapeutic effect conceived in the research stage is effective in humans
2. Technology that integrates computer-based mathematical simulations with biological sciences. Supports key decision-making during pharmaceutical development.
3. Tissue structures designed to have similarities to organs in the human body

Late-Stage Clinical Development

In late-stage development, we are currently conducting over 100 studies primarily in Japan. As R&D output will further increase in the future, improving productivity by changing operational models is an urgent issue. We will actively use digital technologies for monitoring and management tasks, and at the same time, we will promote reductions in the size and duration of studies through the use of RWD. In this way, we aim to deliver products to the market faster and reduce the burden on patients.

Our target for late-stage clinical development is to double productivity by 2030.

Case Studies

Development of New dBMs

Sayumi Higashi
Digital Strategy Department

The use of dBMs is significant in that it enables more appropriate diagnosis and treatment by continuously and quantitatively measuring the biological information of patients. dBMs are expected to play an important role in the future of medical care, contributing to more immediate and efficient diagnoses, supporting the accumulation of data for evaluation, and being applied in drug discovery.

For example, from the end of 2018, I have been responsible for developing dBMs for endometriosis. This condition is particularly problematic, as patients find it difficult to accurately communicate their symptoms to doctors during consultations, and it has not been possible to measure frequently enough to detect changes in subjective symptoms such as pain in order to measure outcomes. To address these issues, Chugai is currently working with Biofourmis on the development of digital solutions that use AI algorithms and biosensors for continuous and objective measurement of pain and reporting to physicians.

We will continue to focus on the development of various dBMs in the future. It is important, however, to carry out a process of in-depth analysis of measurable items and choose the right technologies, because medical challenges and needs differ depending on the disease and product. My goal is to build up a track record in development and create development schemes.

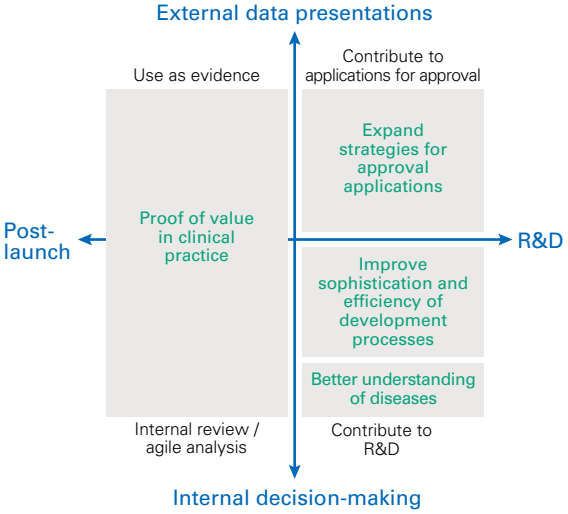
dBMs are an extremely new technology, so the healthcare industry is also only just starting to develop methods and frameworks for dBM use and data application. Measures to protect personal information and other security issues are essential. To maximize patient and product value, Chugai will support the establishment of new diagnostic and therapeutic frameworks for the industry and take a leading role in the discussion over best practice.

E4 wristband*
Source: Empatica company website
* Wearable device being tested for the development of the endometriosis dBM

Initiatives for Using RWD

In the future, the use of RWD, including health insurance claims and electronic patient records, is expected to enhance the efficiency and sophistication of healthcare in various ways, such as improving patient value, selecting better treatment strategies, and understanding the actual medical conditions of patients in real time. However, there are numerous national, regulatory, and healthcare system-related issues that need to be addressed first, including ensuring that the quality and quantity of the data is suitable for use in regulatory submissions, and establishing highly transparent analytical methods and infrastructure. Against this backdrop, Flatiron Health Inc., a Roche Group company, collects and regularly updates the electronic medical record data of 2.2 million cancer patients, and is working with academia, pharmaceutical companies, and the U.S. FDA on initiatives to utilize a wide range of RWD.

Chugai is also working in collaboration with Flatiron Health to build environments where RWD can be used in a timely and appropriate manner. The figure to the right summarizes our initiatives in four different areas. For example, in the section on expanding strategies for regulatory submissions, we have added RWD as reference data to the application documents for a drug in patients with ROS1-positive lung cancer. At academic conferences, we have also presented on the incidence of infections in patients with lupus nephritis and rheumatoid arthritis, and are working to enhance the sophistication and efficiency of the development process.



3. Pharmaceutical Technology

Realize pharmaceutical technology functions befitting a top innovator by combining high cost competitiveness with world-class technologies for turning drug discovery ideas into drugs

Early-stage development

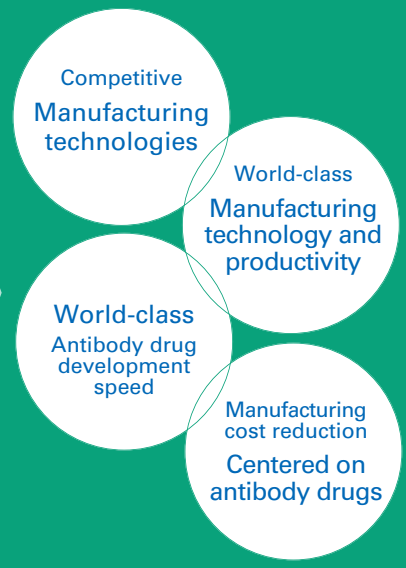
Pursuit of world-class technologies

- Strengthen collaboration with drug discovery, making full use of state-of-the-art technology to manufacture drugs of high difficulty, such as mid-size molecules and highly active substances
- Evolution of the world's most advanced antibody technology and realization of development speed

Late-stage development

Pursuit of cost competitiveness

- Establishment of a manufacturing system that balances the strengthening of manufacturing technology functions and cost efficiency
- Maximization of productivity by promoting a second-site strategy and utilizing digital and robotics technologies



Early-Stage Technology Development

In the area of early-stage technology development for pharmaceutical technology, which is a component of the Research and Early Development (RED) function, our priority is to pursue world-class pharmaceutical technologies in terms of both technological sophistication and development speed in order to ensure the commercialization of innovative pharmaceuticals while responding to the significant expansion of R&D output. Development programs involving mid-size molecules, highly active substances, and new modalities—all addressed in the TOP I 2030 strategy—are extremely difficult to formulate. This means that establishing pharmaceutical technologies for these types of products would give us a competitive edge. We will further strengthen collaboration between the functions of drug discovery, development, and pharmaceutical technology; establish technologies for the active pharmaceutical ingredients (APIs), formulation, and analytical technologies of new compounds; and also accelerate the establishment of systems linking investigational drug development and early-stage production in preparation for the global competition in drug development.

For therapeutic antibodies, which are also expected to continue evolving, we will work to achieve world-class development speeds by further advancing manufacturing technologies in response to the advancements in antibody engineering technology. We also plan to actively invest in the human capital, facilities, and technologies needed for these initiatives.

Late-Stage Development and Commercial Production

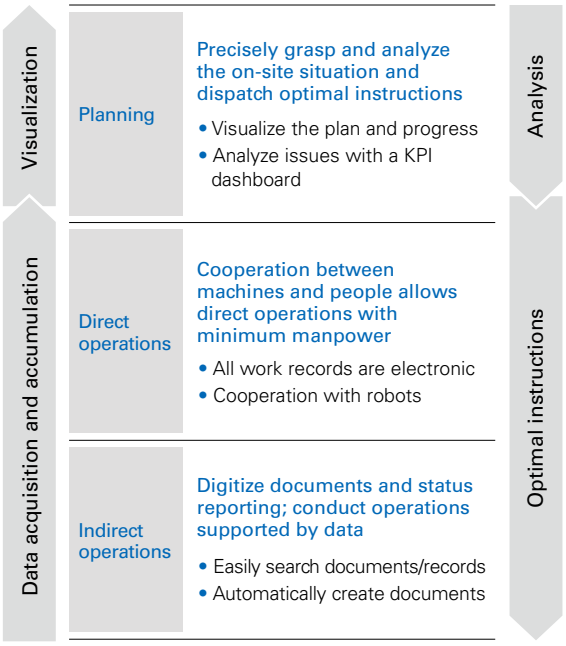
In production functions, we are establishing new systems that balance strengthening production technology functions with low-cost operations to ensure stable supply and improve productivity. We are accelerating efforts to improve production efficiency through the development of IT infrastructure using digital technology, as well as through the realization of digital plants and the application of robotics. As for digital plants, we are currently implementing various measures using the Ukima Plant as a model case, and we have plans to roll out measures to other sites in the future.

To reduce costs, we are developing next-generation biopharmaceutical plants for the production of antibody APIs. Our aim is to achieve significant improvements in productivity by reducing the size of plants and the amount of resources invested. We are currently in the final stages of technology development and plan to introduce pilot facilities in the future. Furthermore, as a second-site strategy, we will consider optimizing commercial production by using contract manufacturing organizations (CMOs) for products that can be outsourced to external partners.

Case Studies

Realization of Digital Plants

Chugai has implemented initiatives to help realize digital plants that can accelerate in-house drug discovery and respond flexibly to changes in the environment. Under the concept of "digitally transforming production operations to increase productivity and add high value to human capital," we are partnering with IBM Japan, Ltd. to link and optimize people and operational data for planning, direct operations, and indirect operations. As a first step, we will establish digital infrastructure to support new operations in the Ukima Plant as our model case by mid-2022 and validate each measure for expansion to other production sites. Conceptualization and requirements definition began in 2020, and implementation of each measure begins from 2021. We will build a digital platform that consolidates various data, including manufacturing, quality, and manpower systems, and utilize it to reform operations for greater efficiency, including planning and progress management, Good Manufacturing Practice (GMP) document retrieval, and remote site support.



Realizing Next-Generation Plants for Biopharmaceuticals

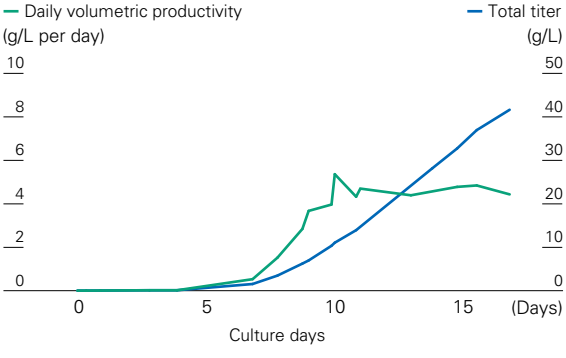
Akihiro Yanagita
API Process Development Department,
Pharmaceutical Technology Division
(Biotechnology)
Professional of Next Generation
Manufacturing & Technology for Bio-Product

Chugai has started to work on developing next-generation biopharmaceutical plants that incorporate continuous production processes, with the goal of achieving substantial cost reductions in the manufacturing of antibody APIs. In continuous production, the non-stop manufacturing processes allow effective use of time and smaller scale plants. When combined with digital applications and robotics, this approach increases operational efficiency and improves productivity.

In the cell culture method that uses "perfusion culture," antibodies are collected while nutrients are continuously provided to a culture tank in which antibody-producing cells mature at high densities. The challenge is to maintain the cells at high densities while increasing antibody production efficiency. We are making steady progress in the development of this method and have reached world-class production efficiency at a lab scale of 4–5 g/L per day (see graph below). For purification processes, we are also working with external parties to link multiple steps, such as chromatography and filtration.

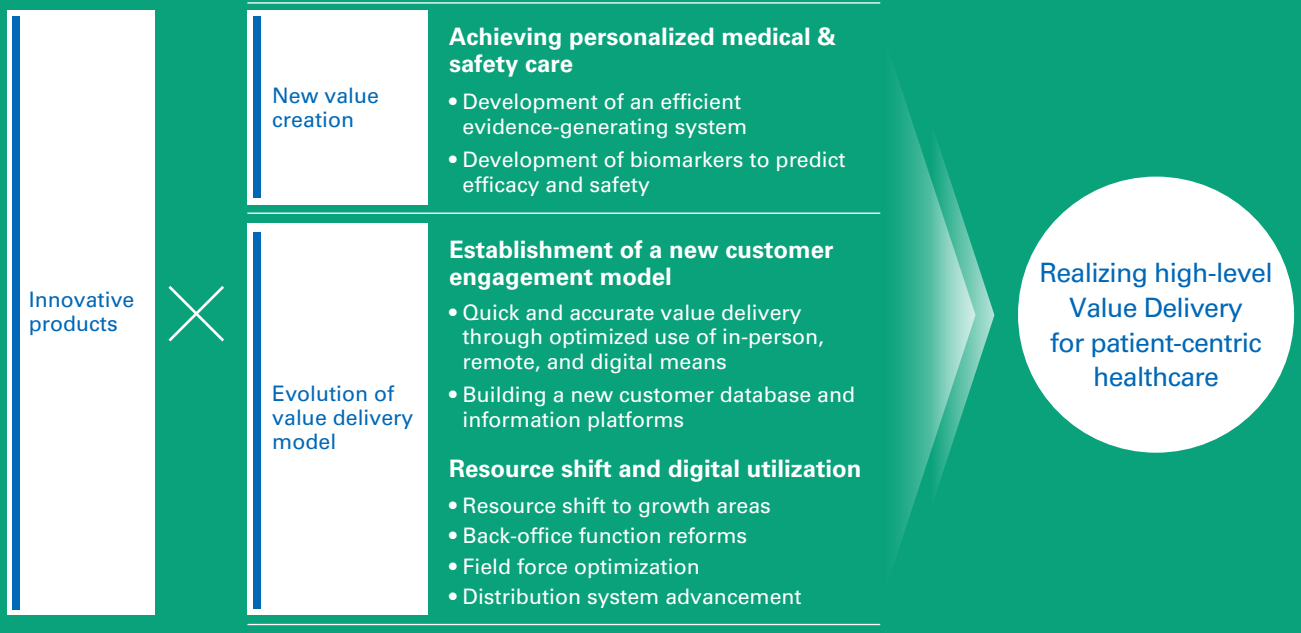
Currently, these technologies are in the final stages of technological development. Prototype equipment for the culture process was installed in 2020, and the scale-up study will start in 2021. We then plan to install prototype equipment for the purification processes in 2022 and test the linking of all the processes. We are making steady progress toward applying these technologies to actual production in the late 2020s.

Efficiency of Antibody Production with Perfusion Culture (Green) and Total Titer Recovered (Blue)



4. Value Delivery

Achieving sophisticated Value Delivery with a limited number of exceptional talents by generating evidence for personalized healthcare (PHC) and building an innovative customer engagement model



Generating Evidence for PHC

As a pioneer in PHC, Chugai has been working not only to develop and supply products but also to promote their use in cooperation with medical facilities and local governments. Under the previous mid-term business plan IBI 21, we focused on the promotion of gene panel testing and the development of genomic cancer medicine as a key strategy to advance PHC. In addition to continuing our efforts in these areas, we will generate high-level evidence to promote PHC through the comprehensive analysis and utilization of various databases and real-world data (RWD) accumulated through drug discovery and clinical development. We will also accelerate the development of biomarkers that accurately predict efficacy and safety for each patient to realize a new phase of PHC.

Establishment of a New Customer Engagement Model

Against the backdrop of the development of digital tools and the impact of the spread of COVID-19, there is a dramatic change in the nature of how we engage with healthcare customers, such as physicians, pharmacists, and nurses. We aim to build a completely new customer engagement model that reflects these changes. Specifically, by optimizing the use of in-person, remote, and digital means and coordinating the sales, safety, and medical functions, which are our major strengths, we will build a solution system that accurately and promptly delivers information truly valuable to customers while maintaining a high level of expertise. To achieve this, we will integrate customer databases with information from various solutions and create a comprehensive interface that allows customer-centric marketing.

Resource Shift and Digital Utilization

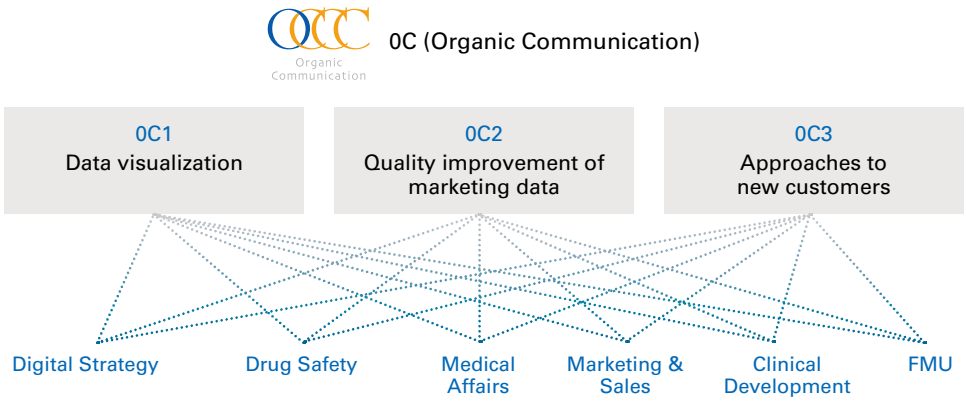
We are planning a bold shift in resource allocation to new and growth areas as well as the optimal allocation of personnel and sites in line with future changes in our product portfolio. In addition, we will implement drastic reforms to our back-office operations, including digitalization, outsourcing, and consolidation of operations.

Case Studies

Building System Infrastructure for Customer-Centric Marketing

In order to respond flexibly to the needs of healthcare professionals, who are our customers, we have launched a cross-departmental project entitled 0C (Organic Communication), or Zero C, which aims to build an integrated interface to realize customer-focused marketing. This will allow management via an integrated database of many different categories of data, from employee activity records to market information on Chugai and competitors, customers, and areas. In this way, we will create a system to support business activities through access to a range of analyses and an AI-based decision support engine. The system will be established as a platform to visualize data, improve the quality of sales data, and facilitate approaches to new customers for each person in charge of various touch points with customers, such as sales, medical affairs, drug safety, clinical development, and Foundation Medicine Unit (FMU).

In addition, we will use the information obtained in this way for marketing purposes, in online seminars, and on PLUS CHUGAI, Chugai's website for healthcare professionals (monthly average unique users: approx. 140,000). We will also integrate the information into MR and digital programs tailored to customer needs.



Promote Advances in PHC

PHC involves using a patient's genomic and other information to provide optimal treatments. This approach has substantial benefits for various stakeholders, in terms of quality of care and health economics, and is at the heart of Chugai's goal to achieving advanced and sustainable patient-centric healthcare. As a pioneer in this area, we are focusing our efforts on a new phase in PHC that can deliver optimal treatment for each individual patient, driven by advances in gene analysis and drug discovery technologies.

One core initiatives is our FMI business, which uses the technology of Foundation Medicine, Inc. (FMI), a member of the Roche Group, to promote cancer genomic medicine. In 2019, we launched FoundationOne CDx Cancer Genomic Profile (F1CDx), a comprehensive cancer gene panel test, and have now obtained approval for its use as a companion diagnostic for Rozlytrek and various other drugs.

In March 2020, we filed a submission for the approval of FoundationOne Liquid CDx as a liquid biopsy test using blood samples, and approval was granted in March 2021. This will enable the test to be used in cases where cancer tissue is difficult to access for biopsy as well as for prognosis prediction and confirmation of post-treatment resistance, thereby supporting a wider range of treatment decisions. Chugai will continue to develop PHC through the adoption of comprehensive genomic profiling.

FOUNDATIONONE® LIQUID CDx

5. Foundation for Growth

Strengthening the foundation for growth necessary to create innovation and evolve the value chain

People and Organization	• Thoroughly implement new HR system • Acquire highly specialized talent • New ways of working • Ongoing promotion of diversity and inclusion (D&I)
Digital	• Create innovative new drugs using digital technology • Streamline entire value chain • Strengthen digital infrastructure
Environment	• Implementation of climate change countermeasures, use of renewable/recycled resources, and biodiversity conservation
Quality	• Acquire approaches for next-generation quality management • Achieve high productivity
Insight Business	• Build capability and seek commercialization through verification and expansion of insight-generating technologies

In parallel with the reforms of each value chain process, we will also work to strengthen our business foundation which supports the generation of innovation and the realization of our growth strategy, especially in the following five priority areas.

People and Organization

Through the operation of the new HR system launched in April 2020, we will work to upgrade our talent management, ensure the right person in the right place, and foster an organizational culture that encourages bold challenges. In addition, we will focus on acquiring, developing, and fulfilling highly specialized talent, such as data scientists and other digital and science talent, who are key to the execution of our strategy. We will make further progress with the D&I initiatives vital for innovation by instilling in employees the three actions of "communicate, discuss, and accept."

Digital

We will promote digital transformation (DX) in each part of the value chain to improve efficiency. Among these, we will focus on the use of digital technologies to create innovative new drugs. We will work to build a digital foundation for both software and hardware in order to achieve this goal. We aim to establish world-class IT platforms through the integration of internal data and creation of a data analysis platform in cooperation with Roche.

Environment

We will push ahead with initiatives to achieve our mid-term environmental goals for 2030 that are based on materiality and external expectations and requirements. For environmental, social, and governance (ESG) issues, we will continue to upgrade our Group-wide initiatives and accelerate the sustainable development of Chugai and society.

Quality

We will strengthen the development and operation of new quality management methods that anticipate changing business processes, such as establishing a new quality assurance system suited to diverse technological advances and the challenge of new modalities, strengthening digital compliance, enhancing collaboration with external parties and developing the Chugai quality brand.

Insight Business

We will explore the commercialization of solutions for healthcare professionals and R&D support solutions based on various insights derived by accumulating and analyzing data obtained across the value chain as well as external data such as real-world data (RWD). In collaboration with Roche, we will expand our capabilities in data analysis and insight extraction, and verify technologies under various different use cases.

Case Studies

Transforming Working Practices as Part of the "New Normal"

Chugai has long promoted the effective use of work-from-home (WFH), but in addition to verifying the status of WFH under the measures to prevent COVID-19 infections, we have now designed new ways of working in the new normal in order to achieve Chugai's new growth strategy. These new working practices are designed to maintain or improve productivity, support quality communication and relationships, and achieve work-life synergies, while at the same time create a system that can flexibly adapt to the needs of the organization, job role, and work tasks as well as individual employee lifestyles.

In terms of detailed initiatives, the working practices encourage each workplace to independently manage whether employees come into the office or whether they work from home or use satellite offices. The system is also designed to improve individual and organizational productivity and to promote digitalization of work processes and the establishment of an IT environment suited to the Telework System. We also need to set up detailed performance-based review systems suited to teleworking, so we will provide training for management skills to achieve this. At our Head Office, we plan to optimize floor space according to the percentage of employees coming into the office for work, and will implement other reforms at the same time to create working spaces suited to value creation through a sense of organizational unity and collaboration.

Envisioned new ways of working

Promote greater digitalization of work processes to achieve more flexible ways of working ("smart working") suited to the needs of the organization, job role, and work tasks, and improve productivity while also achieving work-life synergies with the goal of achieving continuous innovation

Measures to achieve new ways of working

1. Introduction of the Telework System utilizing WFH and satellite offices
2. Creation of an environment that maintains and improves productivity even with flexible ways of working
3. Development of staff performance evaluation and management systems suited to teleworking
4. Review of office plans and various rules in light of the introduction of the new Telework System

Overview of the Main DX Measures to Enhance Our Foundation for Growth

Foundations: Establish digital/ IT infrastructure	• Development of Chugai Scientific Infrastructure (CSI), an IT platform for securely using, moving, and storing large amounts of data, with the aim of promoting company-wide data utilization • Digital transformation (DX) of manufacturing functions to realize digital plants, and establishment of digital infrastructure to support new operations • Establishment of Digital Compliance Committee, formulation of rules and guidelines relating to the handling of human-derived data, and construction of systems capable of responding appropriately in line with risk
Foundations: Reform awareness and culture	• Initiatives to transform awareness and culture in Chugai (Digital Leaders appointed in each division; events to share various departmental digital initiatives across the Company, including Digital Summit and the online event DIGITAL IT HEALTHCARE WEEK for internal and external audiences; information sharing via various in-house channels; support from the Digital & IT Supervisory Division to help progress with all DX initiatives; etc.) • Establishment of the Digital Innovation Lab (DIL) to incubate bottom-up ideas and support their realization, as well as fostering staff trial and error (DIL started operating in June 2020; approximately 150 ideas had been put into practice as of the end of December 2020)
Talent	• Visualization of internal digital talent and skills, preparation of education systems to foster digital talent, and design/implement training programs • Enhancement of recruitment strategy to bring in external digital talent (use new recruitment methods, communication about in-house role models on the official channel on "note," a content platform that supports creators)
Partnering	• Acceleration of external partnerships to make further progress in the various DX initiatives IBM Japan, Amazon Web Services, NTT DATA, Biofourmis, FRONTEO, Preferred Networks, LINE WORKS, Welby • Launch of DigiTube online corporate briefing; held regularly, the briefing features presentations by tech companies on the latest technologies to inspire Chugai employees, regardless of their department or job role, and helps to facilitate business matching between employees and tech companies (presentations and technical materials from over 30 companies each year are available for all employees to access)