

# COMMITMENT TO PATIENT

We discover and deliver life-transforming treatments, guided by our commitment to patients. Our researchers, together with world-class external partners, translate science into highly innovative, life-changing and life-saving medicines. We are also pushing boundaries to accelerate access to healthcare for more people worldwide.



# Responsibly translating science into highly innovative, life-changing medicines and vaccines

We don't go after easy wins. At Takeda, we are innovators and collaborators who bring forward ground-breaking treatments to patients with significant unmet needs. Our internal labs collaborate with world-class partners to access cutting-edge science wherever it originates, helping us build a modality-diverse and innovative pipeline. Together, with our investments in data and digital, we aim to deliver medicines to patients all over the world.



## The Strength of Our Portfolio and Pipeline

Takeda supports R&D efforts across three areas: Innovative Biopharma, Plasma-Derived Therapies (PDT) and Vaccines. The R&D engine for Innovative Biopharma, our largest R&D investment, has produced a diverse and dynamic pipeline in areas of high unmet medical need across our core therapeutic areas where we have deep expertise: oncology, rare genetics and hematology, neuroscience and gastroenterology.

Our pipeline contains approximately 40 new molecular entities, many with the potential to become life-changing treatments in the next decade. Momentum across our portfolio is the result of a robust partnership network and investments in foundational technologies and data sciences. These investments, combined with our expertise, enable Takeda to advance a modality-diverse pipeline and build robust capabilities in new areas.



You can learn more about our pipeline [here](#).

## FY2021 Milestones

Takeda continued to deliver transformative innovation to patients in FY2021 with two major new molecular entity approvals and continued expansion of our growth and launch products. Examples of these milestones that are helping to deliver near-term growth for Takeda include:

### LIVENCITY®

(Maribavir): Redefining the management of post-transplant refractory/resistant cytomegalovirus infection. In 2021, it became the first and only treatment indicated by the U.S. Food and Drug Administration (FDA) for transplant recipients who are 12 and older and weigh at least 35kg.

### EXKIVITY®

(Mobocertinib): The first FDA-approved oral insertion therapy for patients with EGFR Exon20+ metastatic non-small cell lung cancer whose disease has progressed on or after platinum-based chemotherapy. A rare mutation, EGFR Exon20 insertion+ NSCLC comprises about 1-2% of patients with NSCLC and, until recently, was an underserved cancer that did not have targeted treatment options available.

### VONVENDI®

[Von Willebrand factor (Recombinant)]: The first and only FDA-approved prophylactic treatment to reduce the frequency of bleeding episodes in patients with severe Type 3 von Willebrand disease receiving on-demand therapy — marking a significant advancement for those living with this serious inherited bleeding disorder.

### ENTYVIO®

(vedolizumab): The first treatment indicated in the European Union for patients with moderately to severely active chronic pouchitis, who have undergone proctocolectomy and ileal pouch-anal anastomosis (IPAA) for ulcerative colitis (UC), and have had an inadequate response with or lost response to antibiotic.





## We Go Where the Science Is

In FY2021, Takeda continued to establish strategic collaborations and targeted acquisitions, announcing immuno-oncology “build-to-buy” acquisitions with GammaDelta Therapeutics and Adaptate Biotherapeutics. Both collaborations demonstrate the value of partnering with early-stage innovators to accelerate cutting-edge platforms, which help strengthen our R&D efforts.

Gene therapy is a key area where Takeda continues to invest through strategic research partnerships. Our growing internal capabilities and network of public and private partnerships with companies like Evozyne, Poseida Therapeutics, Selecta Biosciences, Immusoft, Genevant Sciences and Code Biotherapeutics will help us discover and develop differentiated “next-generation” gene therapy programs with the aim to deliver functional cures for patients. Takeda is pursuing development in a number of rare genetic and non-malignant hematological diseases that we believe are ideal for gene therapy, and we expect to expand into other diseases across our neuroscience and gastrointestinal therapeutic areas.



## Partnering to Accelerate Discovery and Development

The challenge of discovering and developing new treatments for genetic disorders cannot be solved by any one organization. We lead or participate in more than 100 R&D public private partnerships across more than 75 countries, dedicating the expertise of our scientists and our data. Many of these partnerships involve patient organizations, top medical centers, leading academic institutions and regulatory agencies working together to better understand patient needs and how best to speed up the development of new treatments. Examples include the [Bespoke Gene Therapy Consortium \(BGTC\)](#), [ARDAT \(Accelerating Research & Development for Advance Therapies\)](#) and [Screen4Care](#).

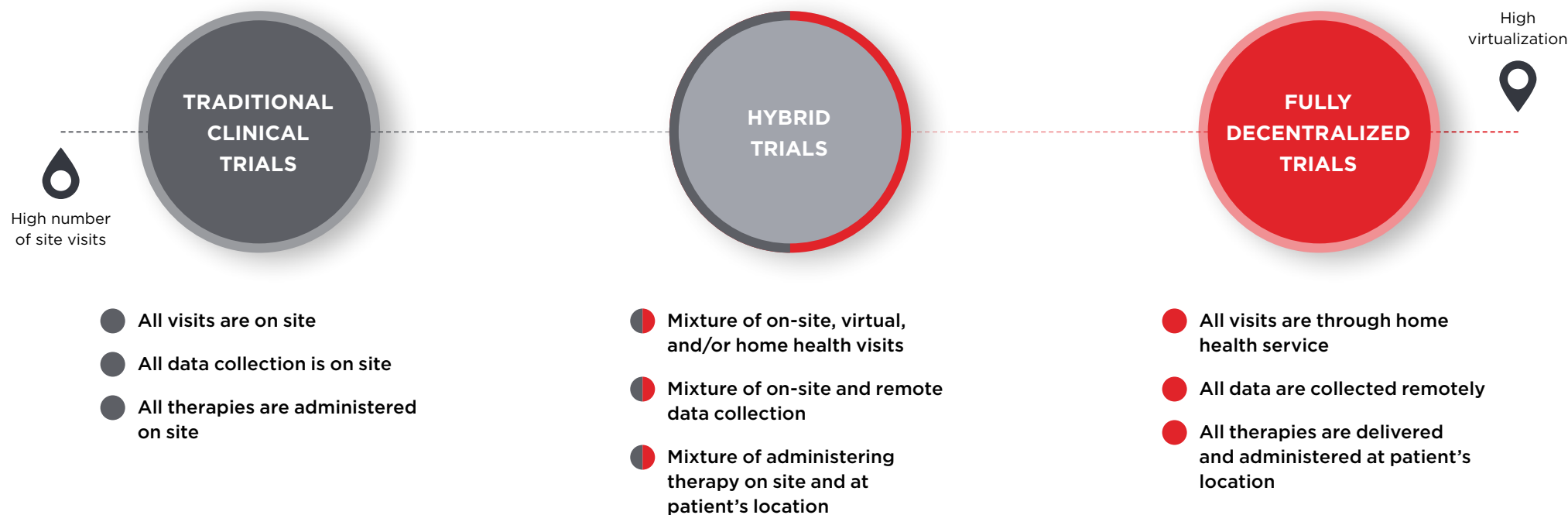
## SPOTLIGHT

## USING DIGITAL TOOLS TO CREATE A NEW, MORE INCLUSIVE ERA IN CLINICAL TRIALS

Until recently, participation in a clinical trial required multiple in-person visits to a medical site, which could be miles from a participant's home and occur at times that may conflict with a participant's work or childcare schedule. For many, the burden of participation was too high to even consider enrollment.

In the future, we envision two models, depending on local regulations: hybrid, which features a mix of on-site and remote participation, and fully decentralized, where all elements of the trial are conducted virtually or at the participant's home. Which approach we take depends on multiple factors and the need to collect data suitable from a regulatory perspective. We believe these approaches will not only help us recruit a wider and more diverse range of participants but will also allow us to do so more quickly, at less expense and with increased participant retention.

Based on patient feedback, we understand that fully virtual trials are not right for everyone. Some patients may not be comfortable with technology or may not have access to reliable internet service. Others prefer the opportunity to meet with fellow patients. For these participants, a mix of on-site and home health visits may be a better solution. But one thing is certain: Designing trials for and *with* patients is the best way to meet their needs.





## Q&A with Gabriele Ricci

Chief Data and Technology Officer

One of the imperatives embedded in Takeda's corporate philosophy is to unleash the power of data and digital to drive innovation for the benefit of patients, our colleagues and the planet. In early 2022, Gabriele Ricci became the company's first Chief Data and Technology Officer. Learn more from Ricci on the exciting transformation taking place at Takeda and the possibilities that await.



[Learn more](#)

## Using Data and Digital to Advance Patient-Centered Care

In FY2021, we supported the Health Outcomes Observatory (H2O) for the second year of a five-year program.<sup>1</sup> The initiative strives to create a patient-centric data-sharing ecosystem, fueled by technology partners who will provide patients with tools to measure their health outcomes in a standardized way, and at the same time give them full control of their data, including deciding who can access it. Dashboards based on patient-reported outcomes (PROs) will be



[Learn more](#)

available to patients and their healthcare providers to help patients track their own health and drive more informed conversations with their providers.

If patients choose to share their data more broadly, it will be anonymized and stored securely by H2O. Together, data will provide valuable insights on the burden of disease and the value of treatment among key populations. This is expected to help researchers, regulators, payers and others identify where additional research into new treatments is most needed and investment of finite healthcare resources can have the greatest impact on public health.

### By creating a standardized framework, H2O hopes to:

- Improve the dialogue between patient and healthcare provider, so that patients receive better care
- Improve healthcare professional's access to data to inform their clinical decisions
- Ultimately improve the quality and sustainability of care based on outcomes that matter to patients

H2O is the first-ever unified attempt to collect and incorporate PROs into healthcare decision-making at individual and population levels. Takeda has taken a leading role in driving the implementation of the initiative, along with other biopharma companies, academics, hospitals, regulatory authorities and payor agencies.

Key achievements in FY2021 included the development of a multi-stakeholder governance model; a milestone collaboration with the Dutch National Health Care Institute, The Danish Medicines Agency, Danish Health Data Authority and Aarhus University Hospital; and the publication of a standardized set of PROs.



## Q&A with Ramona Sequeira

President  
Global Portfolio Division

In early 2022, Ramona Sequeira was named President of the company's new Global Portfolio Division. She will create a unified global organization to power our launch capabilities, allowing us to accelerate access of our new, life-transforming therapies to more people worldwide. In 2022, she also took on the role of Chair of the Pharmaceutical Research and Manufacturers of America (PhRMA) board of directors. Learn what Sequeira believes is key to building trust, expanding access and maintaining a thriving biopharma sector key.



[Learn more](#)

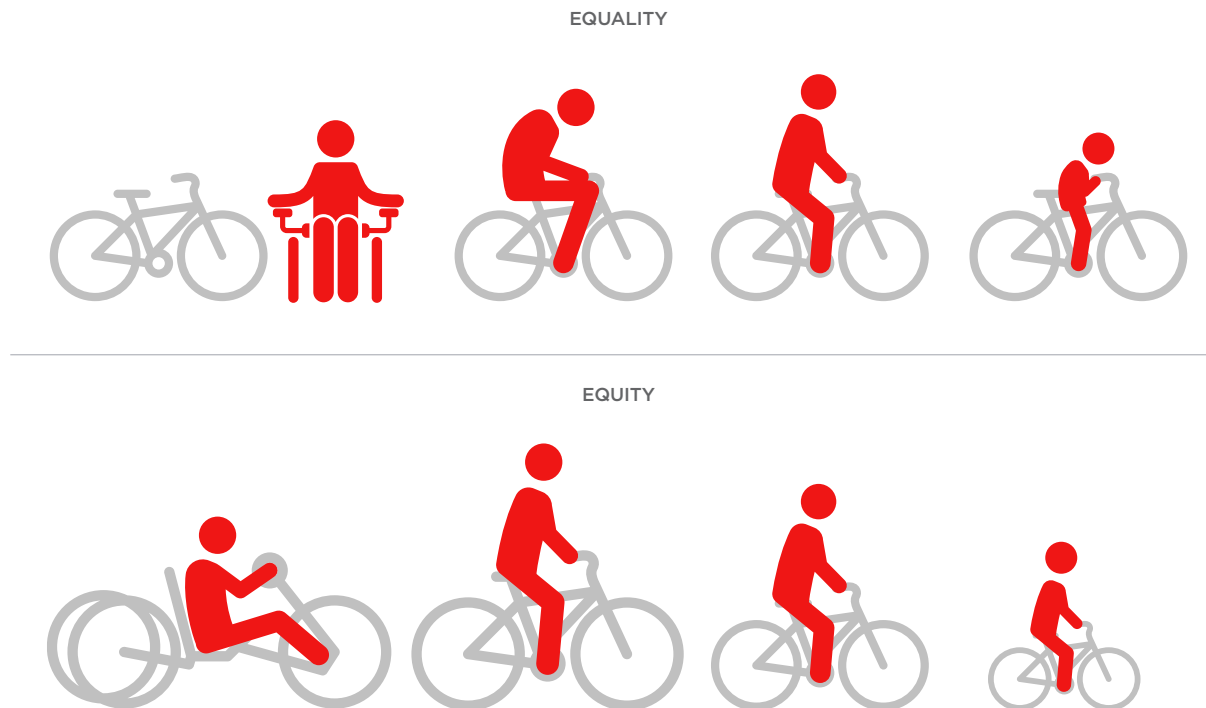
<sup>1</sup> H2O is one of our public private partnerships sponsored by the European Innovative Medicines Initiative.

## Addressing Health Inequity

Through the Takeda Center for Health Equity and Patient Affairs (HEPA), launched in 2020, we are collaborating with diverse partners, including patients, communities and organizations, as well as public and private organizations, to identify and address health inequities in communities. Within Takeda, HEPA sits at the intersection of research and access activities, serving as a center of excellence to all business units.

Equity starts with understanding. Once we understand diverse patients' needs and the communities in which they were born, grow, live, work and age, we can create more inclusive practices and develop innovative medicines that better reflect how patients wish and need to engage with healthcare to achieve their highest level of health.

### What is Health Equity?



Health equity means that everyone has a fair and just opportunity to be as healthy as possible. This means addressing social determinants of health, e.g., poverty, racism, discrimination, unemployment and other barriers that impact our ability to be healthy and disproportionately impact disadvantaged and underserved communities and patients.

*This illustration is based on the original 2017 Robert Wood Johnson Foundation's "What is Health Equity" graphic.*

## Raising Awareness

Takeda's Center for Health Equity and Patient Affairs (HEPA) and Springer Nature, a leading provider of trusted scientific information, are coming together to raise awareness of health inequity around the world. The [Scientific American Collection](#), an editorially independent digital collection of articles about health equity, produced with support from Takeda and published in December 2021, aims to spur awareness and new ideas to improve equity and health outcomes. In June 2022, *Scientific American* also published an [Innovations In](#) special report focused on health equity, which includes a video documentary.

HEPA is also proud to sponsor an annual global conference, Nature Café, on health equity with leading health experts in the field, scheduled to occur for the first time virtually in late 2022. In addition, HEPA is supporting a new global Nature Awards program that will shine a light on existing best practices and people making a difference in delivering inclusive health research to address health inequities. It is expected to open for submissions in September 2022.

One of our newest health equity partnerships in the United States is in Louisiana, a state which ranks lowest in health outcomes in the country.<sup>1</sup> The Takeda-Xavier University of Louisiana Partnership for Improved Health Outcomes seeks to:

- **Build trust** with historically underserved communities
- **Increase diversity and health equity expertise** of graduate and postgraduate public health researchers and PharmD's
- **Develop enhanced methodologies** to use health informatics to advance equitable science and clinical care and patient outcomes
- **Encourage participation** in clinical trials with a focus on underserved communities
- **Enhance care models** by addressing social determinants of health

We also launched a partnership in 2021 with Remote Area Medical (RAM), which helps local communities provide free dental, vision and medical services to patients in rural, underserved areas of the United States. Our support will help RAM operate pop-up clinics in additional communities.



<sup>1</sup> United Health Foundation Rankings



# Accelerating Availability and Access to Improve Lives Worldwide

We work to provide timely, broad and sustainable access to our global products worldwide, including in underserved communities and countries with evolving healthcare systems where there are no medical alternatives. The first step post regulatory approval is working to ensure product availability and supply.

## Global Product Availability

We are committed to registering our growth and launch products where there is need and the infrastructure to support their secure and sustainable delivery to patients, as illustrated by our approach to registering our investigational dengue vaccine.

Dengue is the fastest-spreading mosquito-borne viral disease in the world, estimated to cause 390 million infections each year. Half the world's

population currently lives under the threat of dengue. In 2021, Takeda's dengue fever vaccine candidate (TAK-003) became the first investigational candidate to participate in the European Medical Agency's (EMA) parallel assessment of a medicinal product for use in the European Union (EU), and through the EU-M4all procedure, for countries outside of the EU, particularly low- and middle-income countries.



## Ensuring High-Quality Supply

We are committed to providing uninterrupted supply of life-changing medicines and vaccines, and to maintaining strict quality standards and effective supply chain management to ensure their safety and security.



Learn more about our approach to product safety and quality.

### Accelerating Supply of COVID-19 Vaccines in Japan

Takeda has stepped up to help ensure supply of COVID vaccines in Japan.

Through our collaboration with Novavax, a technology transfer is being executed at our Hikari facility to allow for the local development, manufacturing and commercialization of Novavax' COVID-19 vaccine candidate (TAK-019). We have a commitment from the Government of Japan's Ministry of Health Labour and Welfare (MHLW) to purchase up to 150 million doses.

In 2021, we imported and distributed 50 million doses of Moderna's COVID-19 vaccine (Spikevax™) as part of a three-way partnership with Moderna and MHLW. In 2022, we are implementing agreements to import and distribute an additional 93 million booster doses.<sup>1</sup>

<sup>1</sup> Takeda will transfer the marketing authorization in Japan for Spikevax™ to Moderna as of August 1, 2022.

## SPOTLIGHT

### PLASMA-DERIVED THERAPIES

#### Improving the End-to-End Donor-to-Patient Process

Treatment with plasma-derived therapies can significantly improve the quality of life and life expectancy of people who live with a variety of rare and complex chronic diseases. Very often, plasma therapies may be their only treatment option. With earlier diagnosis, increased screening and improved standard of care for these diseases, the number of people around the world who can benefit from plasma-derived therapies is rapidly growing.

To meet accelerating demand, we committed to increase our plasma supply and manufacturing capacity by >65% by end of FY2023 (from a FY2018 baseline).

#### Key Milestones

- Met all supply commitments to patients worldwide in 2021 and grew market share despite the impact of COVID-19
- Surpassed pre-pandemic donation volumes consistently by end of June 2021 — the only company to do so in CY2021
- Grew network of donors by 56% since FY2018

### AT A GLANCE | Takeda's Plasma-Derived Therapies Business Unit

- > 20 plasma medicines supplied to patients in more than 80 countries
- > 200 high-quality BioLife donation centers in the U.S. and Europe
- > 8 world-class plasma manufacturing facilities

#### Reaching More Patients through a Differentiated Donor Experience

Unlike traditional pharmaceutical products, plasma cannot be replicated in a lab. Plasma must be donated by healthy individuals.

Recognizing the need for — and importance of — attracting more people to donate, we are expanding the number of BioLife Plasma donation centers available for donors. Since 2018, we have increased the number of centers by more than 100 — and we are doing so sustainably by building all new U.S. centers as all-electric facilities, starting in September 2021.

In 2021, we completed the migration of all our U.S. BioLife Plasma Services donation centers to the cloud, creating an enterprise-wide intelligence engine with robust AI-driven capability that will enable us to collect, connect and

It can take up to

# 1,200

plasma donations to treat one chronically ill patient for one year.

Since its launch in May 2021, Success Coach has had more than

# 8,000

unique users, and nearly 3,000 return users.

exchange real-world data securely. By transforming this data into actionable insights, we expect to deliver larger plasma donation volumes and faster processing times.

Similarly, we are attracting more donors by combining cloud-based data-driven insights with industry-leading omnichannel engagement, providing donors with a more personalized experience. We launched our live Facebook chatbot "Success Coach" — the first-ever AI virtual assistant for potential donors in the United States. The bot provides a personalized chat experience with potential donors, answering questions and providing useful tips and instructions for registering and preparing to donate.

## Sustainable Patient Access

Takeda believes an integrated, collaborative and sustainable approach to patient access can help address the challenges health systems and patients face around the world. Because health systems and access challenges differ both between and within countries, we tailor our approach, working with local stakeholders, based on country needs and demographics (including income).

Our actions are guided by our global access strategy, which includes:

- **Collaborating with partners** to strengthen healthcare systems
- **Investing in programs and solutions** that address affordability barriers and enable access, including:
  - Tiered pricing
  - Patient assistance programs
  - Value-based healthcare models
- **Working with policy makers** to broaden patient access

### Solutions to Address Affordability Barriers and Enable Access

Our value-based approach to healthcare begins with how we price our growth and launch products.

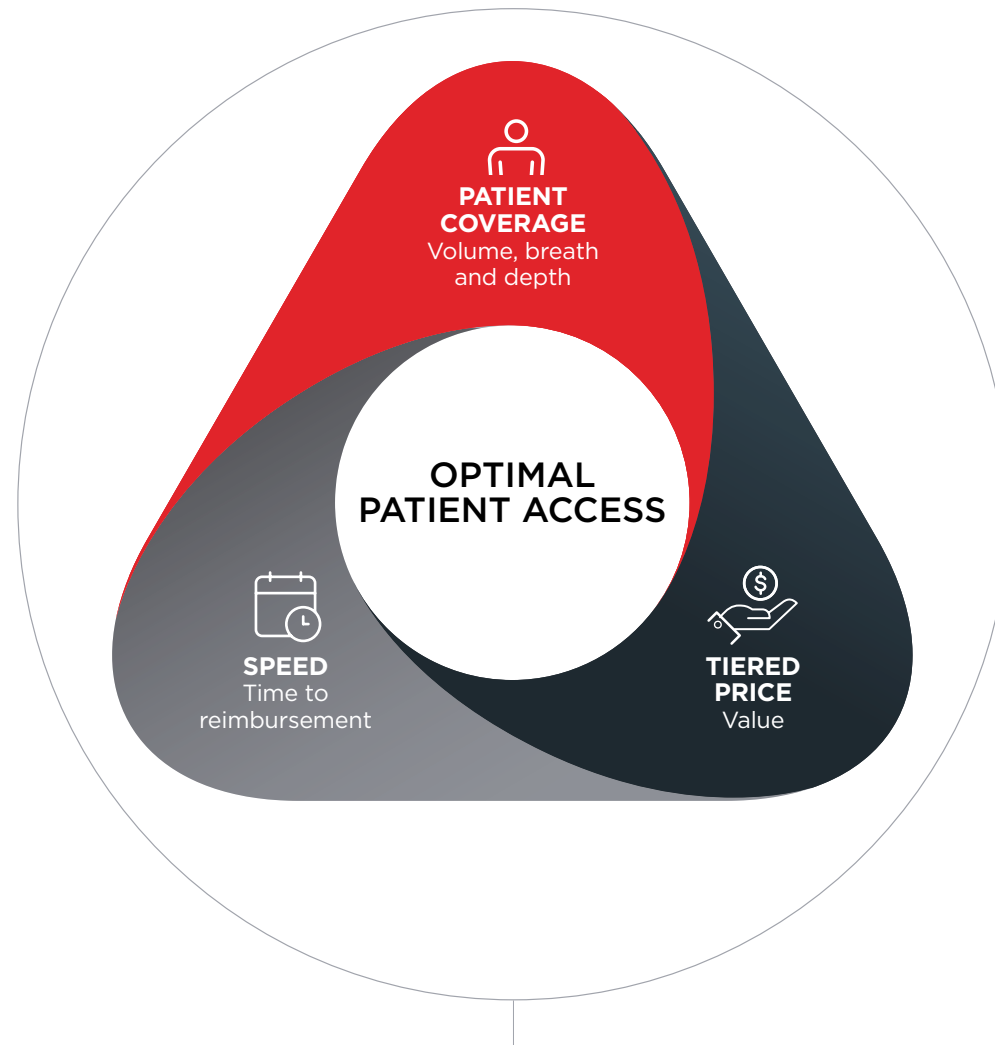
We price our medicines in line with our value-based pricing principles to reflect the holistic value they offer to patients, the healthcare system and society. We are committed to establishing responsible prices that are acceptable to payors and society.

### Strengthening Access to Medicines in Countries with Evolving Healthcare Systems

While barriers to access exist around the world, those most acutely impacted are underserved communities in countries with evolving healthcare systems or limited access to resources. Barriers to access within, and between, populations range from the levels of capacity and resources needed to prevent, educate and raise awareness of care, to the specialized skills needed by healthcare providers to screen, diagnose and treat patients.



Read more about our approach to [Access to Medicines](#) and [examples of our programs](#).



### Takeda Pricing Principle

Optimal patient access encompasses the speed of access and the breath of coverage at a price that leads to a sustainable business.

We recognize that affordability varies by country. That is why we price our products relative to a country's economic stage and health system maturity through our tiered pricing approach. We group countries into four pricing tiers based on factors such as Gross Domestic Product (GDP), out-of-pocket expenditure and policies covering vaccinations, rare diseases and available healthcare resources per citizen. Tiered pricing helps us deliver life-changing treatments to as many patients as possible, as quickly as possible.

We also offer patient assistant programs (PAPs) in many countries to support patients who have difficulty accessing our medicines. Many include collaborative financing models tailored to the individual patient and the socioeconomic context and health frameworks of the country in which the patient lives.

### Value-based Health Care Models

Another way we are increasing access to our medicines is through value-based health agreements with payers. These approaches help payers and providers manage uncertainty around the clinical performance and economic impact of our medicines through pricing agreements based on the actual performance of our medicines against agreed-upon outcomes within their patient populations. Because value-based or outcome-based arrangements are long-term commitments, they are a "win-win-win" for patients, payers and Takeda.

### Supporting Value-Based Healthcare through Partnerships

We believe that a value-based approach to healthcare can lead to a better allocation of resources in health systems and better health outcomes for patients and society. We're working with stakeholders to build support for the approach and for the health data needed to make it a reality.

As a member of the World Economic Forum's Global Coalition for Value in Healthcare, we share learnings and work with others to develop methodologies and tools to scale health system transformation across geographies and population segments and facilitate value-based healthcare partnerships.

In addition, in 2021, we entered a partnership with the Global Surgery Foundation and the United Nations Institute for Training and Research to facilitate locally led initiatives that will promote and advance the implementation of value-based healthcare in low-income and resource-limited settings with a focus on NCDs. Takeda is supporting pilot projects in Turkey, Rwanda and South Africa.

In 2021, we also joined RWE4Decisions, a payer-led, multi-stakeholder learning network about the use of real-world evidence (RWE). The initiative seeks to forge agreement on the use of RWE to better inform decisions by healthcare systems on introducing new health technologies, including medicines, for patients with high unmet needs.



Within emerging markets, we have implemented innovative means-tested PAPs in 17 countries and territories.



#### For more information

[Position on Global Pricing](#)

[Position on Value-Based Healthcare](#)