Patient

Metric and results:

Achieving Pipeline Milestones

18 regulatory approvals and pivotal study starts (FY 2022) ☑

Background:

Takeda Pharmaceutical Company Limited and its consolidated subsidiaries (referenced hereafter as "Takeda" or "the Company") focuses on diseases with the highest unmet needs to deliver high quality life-transforming medicines and vaccines to patients as quickly as possible. Regulatory Approvals and Pivotal Study Starts are important milestones demonstrating our progress to bring new treatments to patients.

Definition:

This metric measures the achievement of Regulatory Approvals and Pivotal Study Starts across different assets, indications and geographies (US, EU, Japan, China, Emerging Markets). Pivotal Studies are defined as registration-enabling clinical trials; trials that are intended to generate data in support of filing for regulatory approval. Pivotal Study Start is defined as the first patient dosed in the pivotal study.

Calculation Method:

Sum of the absolute number of Regulatory Approvals and Pivotal Study Starts in the reporting period (fiscal year). The counts in this formula include the US, EU, Japan, China, and Emerging Markets. Pivotal Studies that are global are counted as one Pivotal Study Start, not separately for each region included in the study.

Scope:

All Therapeutic Areas, Plasma Derived Therapies, Vaccines

Metric and results:

Disclosing Clinical Trial Results

100 % (FY2022) ☑

Background:

Takeda is committed to compliance with clinical trial transparency laws and regulations as well as to providing objective, unbiased clinical trial results reporting, regardless of outcome, including making clinical research information and results available to the public. Our policies meet or exceed the pharmaceutical industry's guidelines and best practices relating to the disclosure of clinical trial results on public registries and websites within one year after trial completion (including results from phase 1 interventional clinical trials, which is not required by law).

Definition:

This metric measures clinical trial summary results disclosed within one year of trial completion, regardless of trial outcome.

Calculation Method:

Percentage of achievement for timely disclosure of clinical trial summary results on public registries, such as clinicaltrials.gov and EudraCT, and Takeda's clinical trials website, clinicaltrials.takeda.com, which require disclosure within one year of trial completion.

[# of clinical trials with results released to public registries and websites within one year of trial completion] / [# of clinical trials with results requiring disclosure (i.e., clinical trials completed and terminated one year ago)] *100 %

Scope:

While Takeda has been registering and disclosing clinical trials results for company-sponsored research since 2002, for the purpose of this metric, which was established in 2021, only those studies completed in the FY21 fiscal year (i.e., between April 1, 2021 and March 31, 2022) for which results were due to be posted within one year of trial completion were evaluated and considered.

- Scope of studies: interventional phase 1 - 4 trials completed and terminated between April 1, 2021 and March 31, 2022. Studies which were divested, or for which an extension of the deadline for results disclosure on clinicaltrials.gov was granted as per regulation/PHS Act during the reporting period, have been excluded from the scope of this metric.

- Scope for disclosure websites: clinicaltrials.gov and Takeda's clinical trials website (ClinicalTrials.Takeda.com) for all studies from all regions; EMA's Clinical Trials Registry (EudraCT) for all studies conducted in the EU.

Additional Information:

https://clinicaltrials.takeda.com/

Metric and results:

Maintaining Uninterrupted Supply

99.3 % (FY2022) ☑

Background:

It is important to ensure uninterrupted supply and delivery of our medicines and vaccines to people by managing our complex supply chain in an agile and sustainable way.

Definition:

This measures our ability to dispatch products to our customers accurately and in a timely manner.

Calculation Method:

Maintaining Uninterrupted Supply measures whether a received order line is dispatched on-time-in-full (or "OTIF", i.e. the dispatch happened on the date requested by the customer and in the volume requested by customer), for any dispatch of finished or traded goods from a Takeda entity to an external customer (pharmacies, hospitals, wholesalers, etc.) GMS (Global Manufacturing and Supply) Service Level number is the percentage of orders that have been dispatched successfully on-time-in-full over the total number of order lines.

In case of delay to the dispatch directly caused by customers (outstanding payments above credit limit/delay of pick up by customer/shipment consolidation with a later shipment/etc), the line is accepted as dispatched OTIF.

[# of order lines dispatched on-time-in-full] / [Total # of requested order lines]

Scope:

All dispatches to external customers (pharmacies, hospitals, wholesalers, etc.) operated by Takeda or on behalf of Takeda. Data related to services to Teva Takeda Pharma LTD where Takeda is providing last mile distribution services post-dispatch are excluded.

Metric and results:

Upholding Manufacturing Quality

100 % (FY2022) ☑

Background:

It is important for Takeda to maintain a good reputation and remain in good standing with health regulatory authorities ("Health Authorities") so that Takeda can continue to deliver our high quality medicines and vaccines to patients. Inspections can result in routine observations which Takeda responds to in a timely manner. The main criterion of the metric is the number of critical observations that result in any negative regulatory action by the Health Authority after the response has been submitted to the Health Authority following a Good Manufacturing Practice ("GMP") inspection.

Definition:

Critical observations are observations from Healthy Authorities which result in negative regulatory action by the Health Authority, including warning letter, drug removal, or a GMP certificate withdrawal.

Calculation Method:

Successful Health Authority GMP inspections are a measure of the health of our Takeda quality system. The annual result is based on the number of Health Authority GMP inspections without any critical observations (observations which result in a negative regulatory action, such a warning letter or a GMP certificate withdrawal). The metric measures the percentage of Health Authority GMP inspections with no critical observations that resulted in negative regulatory action, with a 100% success rate as the target.

[# of health authority inspections without critical observations] / [# of health authority inspections]

Takeda reviewed its global Health Authority GMP inspection data for FY2022 for critical observations covering approximately 400 inspections conducted globally by a variety of Health Authorities. For FY2022, there were no critical observations that resulted in negative regulatory actions recorded for Takeda.

- For the evidence of the critical observations, the data was obtained from Takeda's internal system.
- The fact that no critical observations were identified also confirmed that no negative regulatory actions based on critical observations occurred.

Scope:

All Health Authority GMP Inspections executed at Takeda locations.

Metric and results:

Access to Medicines Programs in Low- and Middle- Income Countries and Evolving Healthcare Systems

1,366 patients (FY2022) ☑

Background:

We believe broadening access to our life-transforming medicines and vaccines in underserved communities requires an integrated, sustainable approach to address barriers to access. Addressing affordability barriers to access is a key focus of our Access to Medicines approach. Takeda's affordability-based Patient Assistance Programs are one of our approaches to address the affordability barrier.

Definition:

Patients enrolled in Takeda's affordability-based Patient Assistance Programs within a fiscal year. Enrollment in the PAP is subject to both individual means-testing to evaluate a patient's ability to pay for treatment and medical eligibility criteria.

Calculation Method:

Number of newly enrolled patients in Takeda's affordability-based Patient Assistance Programs over the fiscal year.

Data Sources	Implementing partners' reports
Key assumptions	• Patient numbers are validated by external partners and submitted to Takeda monthly. • External partners' reports are subject to quality control processes prior to submission to Takeda. • A patient is considered enrolled when the patient provides a validated proof of purchase for the first course of medication. • A patient who exited the program and subsequently re-enrolled is counted as 2 patients.
Limitations	No limitations on ensuring reported numbers are correct in all material respects.

Scope:

Programs in scope	Affordability-based Patient Assistance Programs
Out of Scope	Charitable Assistance Programs, Named Patient Programs, Post-trial

Programs	Access Programs, Institutional Requests for Unregistered Products, Individual Patient Requests, Non-affordability-tested Patient Assistance Programs, product donations (i.e., disaster relief)
Countries	Countries where Patient Assistance Programs are currently in place: Lower- and middle-income countries and countries with evolving healthcare systems* *Low Income, Lower-Middle Income and Upper-Middle Income countries per the World Bank, and Qatar, Singapore and United Arab Emirates.
Therapeutic areas	Takeda has currently implemented Patient Assistance Programs for the following therapeutic areas: Rare diseases, Gastroenterology, Oncology, Plasma-derived therapies