RANK	SCORE
16	2.21
14 (2022)	

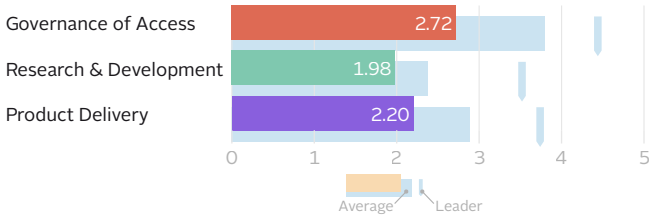
Gilead Sciences

Stock exchange: NASDAQ • Ticker: GILD • HQ: Foster City, California, United States • Employees: 18,000

PERFORMANCE IN THE 2024 INDEX

16th place. Gilead performs below average. It engages widely in voluntary licensing to enable generic supply. However, it has a comparatively poor performance in Governance of Access, and many of its late-stage pipeline projects do not have an access plan.

How score was achieved



OPPORTUNITIES FOR GILEAD

Ensure all late-stage R&D projects have comprehensive access plans. Gilead has a structured framework for access planning. However, it only has access plans in place for 10% of its late-stage R&D projects. By implementing its systematic framework for access planning, the company can ensure the coverage of all pipeline projects from Phase II onwards. For example, Gilead can disclose access plans to its innovative drug domvanalimab, currently undergoing clinical trials for multiple cancer indications.

Ensure access-to-medicine strategy is integrated within its corporate strategy. Gilead's access strategy has a business rationale, which it covers some therapeutic areas that the company is involved in. The company can ensure the strategy is integrated into its corporate strategy and expand it to all therapeutic areas.

Ensure equitable access to lenacapavir in low- and middle-income countries (LMICs). Gilead's blockbuster long-acting injectable, lenacapavir, is currently approved for HIV treatment and has demonstrated promising results in clinical trials for HIV prevention. The company has publicly announced a non-exclusive voluntary licensing agreement with six generic manufacturers to make and sell generic lenacapavir in 120 LMICs (subject to regulatory approvals). It can now work (alongside the generic sublicensees) to ensure fast and equitable access to generic lenacapavir. Furthermore, it must ensure access to affordable lenacapavir, particularly for vulnerable populations living in countries outside of the licensing agreement.

CHANGES SINCE THE 2022 INDEX

- Endorsed the Kigali Declaration on Preventing, Controlling, and Eliminating Neglected Tropical Diseases in June 2022.
- Contributed USD 85mn to the Gilead Foundation to advance health equity.
- Announced a new public-private initiative with the Partnership for Health Advancement in Vietnam to help address barriers that limit viral hepatitis diagnosis and care at primary healthcare facilities in Vietnam and the Philippines.
- Expanded its ongoing long-term donation programme of amphotericin B liposome (AmBisome®) to two additional countries in scope (Eritrea and Yemen) in 2023 to support the elimination of visceral leishmaniasis.
- In June 2024, Gilead's Phase III clinical trial PURPOSE 1, which evaluated the twice-yearly injection Lenacapavir, demonstrated 100% efficacy in preventing HIV infection in cisgender women (a group that shares a disproportionate number of new HIV infections).
- In October 2024, after the period of analysis*, announced it had signed non-exclusive voluntary licensing (NEVL) agreements with six generic manufacturers to make and sell generic lenacapavir. The licence covers lenacapavir for HIV prevention (subject to required regulatory approvals) and for HIV treatment in heavily treatment-experienced adults with multi-drug resistant HIV. The licence covers 120 countries, including 96 counties in scope of the Index.

*As the licence was announced after the period of analysis concluded, it was not assessed as part of the 2024 Access to Medicine Index.

Gilead Sciences

SALES AND OPERATIONS

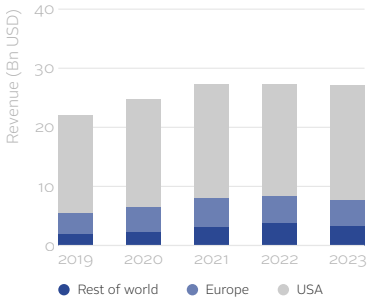
Therapeutic areas: Inflammatory diseases, oncology, viral diseases
Product categories: Innovative medicines
M&A news: Gilead acquired the remaining worldwide rights of Trodelvy® from Everest Medicines for USD 175mn and MiroBio for USD 405mn in 2022, respectively. In 2023, it acquired Tmunity Therapeutics and XinThera for undisclosed amounts. In 2024 Gilead acquired CymaBay Therapeutics Inc for USD 4.3bn.

Revenue by segment (2023) – in USD	
Pharmaceutical	27.12 bn
Total	27.12 bn

Sales in countries in scope

Gilead's products are sold in **41 out of 113 countries** in scope of the Index. Gilead has sales offices in 6 countries and sells via suppliers and/or pooled procurement in an additional 35 countries.

Sales by geographic region

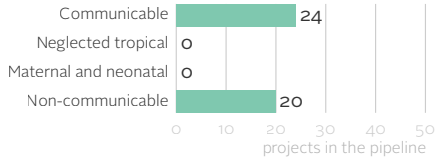


SAMPLE OF PIPELINE AND PORTFOLIO ASSESSED BY THE INDEX

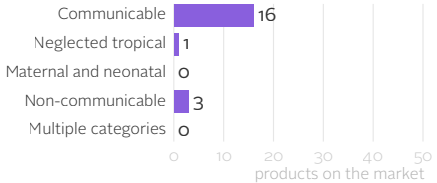
PIPELINE *for diseases in scope*
Gilead has 44 R&D projects in scope, 20 of which target priority diseases, focusing on HIV/AIDS (15) and COVID-19 (4). The remaining 24 projects target other diseases in scope, including cancer (19), hepatitis B (4) and HIV/AIDS (1). Of the 44 R&D projects, 29 are in late-stage development, with evidence of access planning for 10% (3/29) of these.

PORTFOLIO *as selected for analysis by the Index*
Gilead has 20 medicines in scope, 7 of which are listed on the WHO EML. Most of the company's medicines are on patent (17). Its medicines primarily treat communicable diseases, such as HIV (9), hepatitis B and C (5) and 1 medicine is indicated for both HIV and hepatitis B (1). Its medicines for non-communicable diseases target cancer (2) and cardiovascular diseases (1). Gilead also has 1 medicine for neglected tropical diseases that treats leishmaniasis.

44 projects in the pipeline



20 products in the portfolio



Breakdown of projects

	Discovery	Pre-clinical	Phase I	Phase II	Phase III	Phase IV	Approval	Other	Total
Targets established R&D priorities	0	3	6	6	3	0	2	0	20
with access plan				1	1	0	1		3
Other projects in scope			6	11	6	0	1	0	24
with access plan				0	0	0	0		0

Breakdown of products

	WHO EML	Non-EML	WHO EDL	Other	Total
Medicines *on patent*	5	12			17
off patent	2	1			3
Vaccines	0	0			0
Contraceptives	0	0			0
Diagnostics			0		0
Other				0	0

Gilead Sciences

GOVERNANCE OF ACCESS RANK 19 SCORE 2.72

19th place. Gilead performs poorly in this Technical Area. The company provides a measurable patient reach goal and a measurable associated health outcomes goal for its patient reach process, but it does not publicly report the resulting patient reach numbers. Further, it does not disclose sufficient evidence of having controls to mitigate the risk of non-compliant or corrupt activities in countries in scope and does not publicly express any support for the Doha Declaration on TRIPS and Public Health.

The highest responsibility for access lies directly with the Board, namely with the Nominating and Corporate Governance Committee overseeing pricing and access issues. Gilead incentivises its senior executives and in-country managers to act on access to medicine. The CEO also has access-related incentives, specifically related to expanding patient access and improved global health.

Access-to-medicine strategy not fully integrated within the overall corporate strategy, but it does have a business rationale. Its strategy covers some of the therapeutic areas in which the company is involved. Gilead publicly discloses its commitments to access to medicine, but the reported goals, objectives and targets are linked to external global health targets and are not company specific. Reporting is mostly clear, centrally available, and updated regularly in its ESG Report.

Shows comparatively strong commitment to responsible business practices. Gilead sets individual-level targets for sales agents, and incentives are not solely based on sales volume. For some countries in scope, it incentivises activities such as field visits and hospital seminars. The company has a public policy on ensuring ethical interactions with healthcare professionals. It also declares that transfers of value to healthcare professionals (e.g., payments for speaking at symposia) are made at fair market value. However, it only publicly discloses information on such payments in countries in scope if required by law or local regulation.

Has a set of controls to promote ethical conduct and mitigate risk to ensure that governance efforts are not undermined by non-compliant or corrupt activities. Gilead performs moderately in this respect. It has policies to mitigate non-compliance risks, including processes to ensure third-party compliance with company standards and region or country risk-based assessments. However, it does not disclose sufficient evidence publicly or to the Index of fraud-specific risk assessments in countries in scope. Gilead has a code of conduct that guides ethical employee decision-making. No breaches in countries in scope were found in the period of analysis.

Gilead does not publicly share any support for the Doha Declaration on TRIPS and Public Health. It has a publicly available policy on 'Intellectual property and patient access', but it does not align with principles embodied in the Declaration. Further, Gilead states that compulsory licensing should be used by governments as a last resort after exhausting all other options.

Fulfils some criteria with its process for measuring and reporting the patient reach of its AmBisome® donations. The process covers most countries in scope and Gilead publicly provides the metrics. The resulting patient reach numbers are not published regularly, although the company demonstrated improvements to the Index. The process also had a measurable patient reach goal and a measurable associated health outcomes goal.

RESEARCH & DEVELOPMENT RANK 14 SCORE 1.98

14th place. Gilead performs below average in this Technical Area. It has an access planning framework from Phase II onwards, but only applies this to a small number of its late-stage candidates. It does not publicly disclose disaggregated R&D investment data, and the company has some R&D capacity building activities.

Structured process in place to develop access plans during R&D. The process is intended to be applied to all R&D projects in scope, no later than Phase II. The company does not make a public commitment addressing its systematic approach to access planning for LMICs.

Large-sized priority R&D pipeline, compared to peers, with access plans in place for 27% (3/11) of the late-stage candidates. Priority R&D pipeline of 20 projects, including 11 late-stage projects that target a priority gap. The company focuses on various priority areas, including HIV and COVID-19. Of Gilead's 11 late-stage candidates targeting a priority product gap, 3 (27%) have evidence of an access plan in place, including equitable pricing and the inclusion of special populations in clinical trials.

Average-sized pipeline, compared to peers, addressing other diseases in scope, with 0% (0/18) of late-stage projects covered by access plans. The company has 18 late-stage R&D projects targeting other diseases in scope that have not been established as a priority by global health stakeholders. The projects target cancer and hepatitis B. Gilead does not provide evidence of access plans for any of its 18 late-stage projects.

Gilead does not publicly disclose R&D investment data disaggregated by disease category, product type or phase of development. Furthermore, it does not disclose disaggregated R&D investment data to global health organisations.

Two of the three R&D capacity building initiatives included for analysis meet all Good Practice Standards (GPS). One example is a programme to support an early-stage research scientist in their career, focused on the prevention, care and treatment of viral hepatitis.

Gilead Sciences

PRODUCT DELIVERY

RANK 15 SCORE 2.20

15th place. Gilead performs below average in this Technical Area. The company supplies one product through supranational procurement and engages extensively in non-exclusive voluntary licensing. Gilead does not show evidence of engaging in inclusive business models or new intellectual property sharing agreements. It does engage in supply chain and manufacturing capacity building initiatives as well as health system strengthening, but only some meet all Good Practice Standards.

Gilead registers products in 13 countries in scope on average. However, newer products* are registered in 1 country in scope on average. Gilead registers 56% of products assessed in at least 1 of the 10 countries with the highest disease burden. The company's tenofovir alafenamide (Vemlidy®), indicated for hepatitis B, is most widely registered, totalling 35 countries in scope. The company reports engaging in the CARICOM Joint Assessment to facilitate registration for 2 of its products.

Has access strategies for its supranationally procured product in scope. Gilead offers its antifungal, liposomal amphotericin B (AmBisome®), at a not-for-profit price to 116 eligible countries as part of its Global Access Program. However, in 2024, Gilead increased this price by 40% per vial. In addition, Gilead renewed its agreement with WHO to donate 304,700 vials of AmBisome® for the years 2023-2025. As part of this renewed collaboration with WHO, the company also provides financial support to improve access to diagnosis and treatment.

Has access strategies for one healthcare practitioner (HCP)-administered product, with some information found on the outcomes. Gilead has not reported access strategies for its HCP-administered products. For 1 product assessed under this category, remdesivir (Veklury®), indicated for COVID-19 treatment, the company has signed non-exclusive voluntary licensing agreements with generic medicine manufacturers in several UMICs, LMICs and LICs in scope. Gilead reports that since its introduction in 2020, more than 8mn patients living in LMICs have received access to remdesivir for COVID-19 through voluntary licensing, up from more than 7mn in July 2022.

Has access strategies for its self-administered products, but no information on the outcomes available. For 3 of the 5 products selected for analysis, Gilead has access strategy examples in all 3 country income classifications (UMIC, LMIC, LIC). Of the 5 products, 4 are sofosbuvir-based hepatitis C (HCV) treatments, for which the company applies a tiered pricing approach and a ceiling price for governments and NGOs in different countries in scope. In addition, for all products assessed, Gilead has non-exclusive voluntary licensing agreements covering LICs, LMICs, as well as several UMICs in scope. Gilead reports that 2.6mn sofosbuvir-based HCV treatments have been made available since 2013 through voluntary licensing. No further disaggregated information has been disclosed on the outcomes of the strategies during the period of analysis.

Gilead has no public commitment to not file for or enforce patents in any countries in scope.

Publicly discloses product patent status for countries in scope. Like most peers, Gilead publicly discloses patent information for small molecules in scope via the Pat-INFORMED database, including information such as filing date, grant number, grant date and jurisdiction.

Gilead has 11 non-exclusive voluntary licensing agreements to enable generic supply, more than any other company in scope. The licences are for compounds covering multiple indications, including HIV (6), hepatitis C (4) and COVID-19 (1). The terms of all licences are publicly available.**

One of the three manufacturing capacity building initiatives included for analysis meets all GPS. In this initiative, Gilead provides its licensees with technical know-how and support to meet internationally recognised quality standards for production of HIV, hepatitis C and COVID-19 treatments. Manufacturers supported through this initiative are in China, India, Egypt, Pakistan and South Africa.

One supply chain capacity building initiative was included for analysis, but it does not meet all GPS. Despite not meeting all GPS, in 1 initiative, Gilead is providing trainings on forecasting demand and supply to manufacturers in India.

Two of the five health system strengthening initiatives included for analysis meet all GPS. For example, Gilead is collaborating with the Partnership for Health Advancement in Vietnam within a multi-stakeholder coalition that aims to address barriers to diagnosis of viral hepatitis in primary health centres.

Gilead remains engaged in existing IP-sharing agreements with public research institutions and drug discovery initiatives to accelerate drug development. In 1 agreement, Gilead shared IP assets with the Clinton Health Access Initiative and PENTA network to accelerate the development of an investigational dispersible paediatric formulation for HIV containing emtricitabine and tenofovir alafenamide (F/TAF). However, the company has not engaged in new agreements during the period of analysis.

Fulfils most criteria for ad hoc donations. Gilead has policies and supply processes to carry out ad hoc donations rapidly in response to expressed need, with delivery monitored to ensure donations reach patients. However, it does not make commitments, publicly or otherwise, to adhere to the most recent WHO Guidelines for Medicine Donations.

Gilead publicly commits to continue long-term donation programme to support the elimination of visceral leishmaniasis. Its programme is active in 11 countries in scope, with the company extending its commitment to donate amphotericin B liposome (AmBisome®) until 2025.

Fulfils most criteria for mechanisms to ensure continuous supply in LMICs. For example, Gilead works with multiple active pharmaceutical ingredient suppliers.

Gilead does not have a policy for reporting substandard and falsified medicines in countries in scope. It does not disclose, publicly or to the Index, evidence of a policy to report cases of substandard and falsified medicines to national or local regulatory authorities.

No evidence of inclusive business models that meet inclusion criteria.

*Products that received their first marketing authorisation within the last 5 years.

**In October 2024, Gilead announced an additional non-exclusive voluntary licensing agreement for lenacapavir. As the licence was announced after the period of analysis concluded, it was not assessed as part of the 2024 Access to Medicine Index.