IFPMA

Always Innovating

Pharmaceutical Industry Facts & Figures

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The pharmaceutical industry is unlike any other: medicines and vaccines can prolong and save lives.

Trust and integrity are therefore cornerstones of the industry, ensuring ethical innovation and scientific progress.

A commitment to these principles is central to delivering sustainable progress in health outcomes, the next generation of medical innovation, and the positive impact this has on the global economy.

To do this, we work as a trusted and constructive partner with many stakeholders, including patients, civil society, governments, healthcare professionals and companies of all different sizes and expertise.

The impact of the pharmaceutical industry, outlined in this report, is a result of the high ethical standards that makes this possible.

1

The pharmaceutical innovation journey

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KEY FACTS AND FIGURES

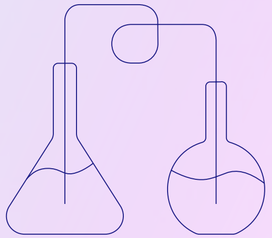
The pharmaceutical innovation journey

USD 167b

The top 50 pharmaceutical companies alone are estimated to have spent a total of USD 167 billion in R&D in 2022. R&D spending has been rising, increasing by almost 60% in the 10 years from 2012 to 2022.

30%

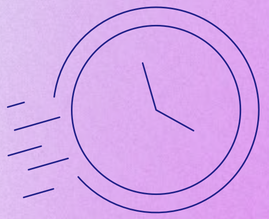
With an R&D intensity of **30%**, the pharmaceutical industry invests substantially more in R&D, compared to other R&D-intensive industries among countries of the Organisation for Economic Co-operation and Development (OECD).



0.01%

Compounds

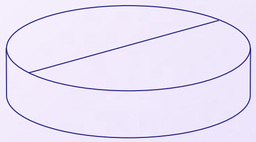
On average, **one or two out of every 10,000 (0.01% or 0.02%) compounds** synthesized in laboratories successfully pass all development stages required to enter the market.



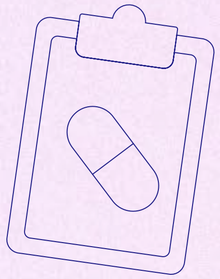
26%

The average time from clinical trial start to patient enrolment close **increased by 26% from 2019 to 2023**, highlighting the growing complexity of pharmaceutical R&D.

10-15 Years



Developing a new medicine is estimated to take **10-15 yrs** with an average cost of **USD 2.6 billion,** considering the cost of failures.



12,555

Patents

In 2023, the pharmaceutical industry **submitted 12,425 patent applications** via the Patent Cooperation Treaty administered by the World Intellectual Property Organization (WIPO).

1. The pharmaceutical innovation journey

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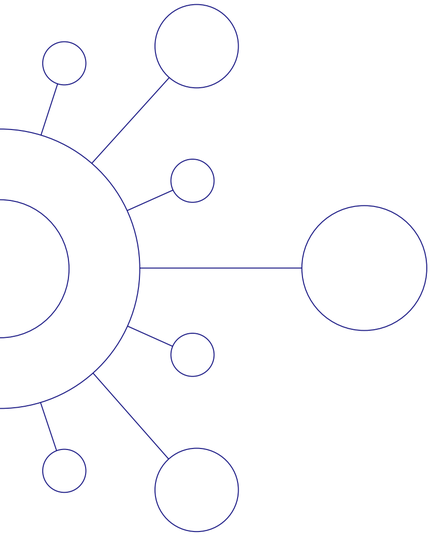
Innovation by the pharmaceutical industry is essential for producing breakthrough products that advance healthcare. Developing a new medicine or vaccine is a complex, costly, and lengthy process. On average, only 0.01% or 0.02% of compounds synthesized in laboratories will make it to market. Only 10% of compounds that enter clinical development progress to market entry. Innovative pharmaceutical companies make substantial investments in high-risk R&D, with clinical trials accounting for about half of their R&D costs. Intellectual property rights (IPRs) are fundamental to protect innovations and to incentivize innovators to embark on the long and risky journey of pharmaceutical R&D. Generics and biosimilars, which are widely used globally, could simply not be produced without IPRs that encourage breakthrough innovations in the first place.

1.1 The innovation ecosystem and the role of intellectual property rights



1.1.1 Pharmaceutical companies' role in the innovation ecosystem

Innovation by the pharmaceutical industry is essential for producing breakthrough products that advance healthcare. Relying on unique scientific and industrial expertise, **pharmaceutical companies take significant financial risks to turn skill and intense research into innovative medicines – often over decades**. This includes translating scientific research into innovative medicines and vaccines, from early-stage research, through clinical development and regulatory review, and into manufacturing.

Pharmaceutical companies provide these solutions thanks to incentives that support research and development (R&D) activity and that enable companies to partner with other stakeholders in certain areas of the innovation value system. The innovation ecosystem is made up of a broad range of different organizations, with the public sector and not-for-profit organizations principally contributing to funding initial basic research aimed at better understanding disease mechanisms and identifying targets for new medicines, expanding general knowledge.[1] Academic institutions, public research groups, and not-for-profit organizations are often involved in medicine discovery through target selection.[1]

Biotechnology companies (biotechs) and small- and medium-sized enterprises (SMEs) often engage in medicine discovery, preclinical development, and early-stage clinical trials, enhancing the pipeline for later stage development.[1] Corporate venture capital (VC) investors may contribute to bringing a medicine to market, helping to bridge the gap between early research and market readiness.[1] Finally, National Regulatory Authorities (NRAs) evaluate medicines and vaccines to ensure they meet international standards of quality, safety, and efficacy before being released for public distribution.[2] **Pharmaceutical companies are involved in all stages of pharmaceutical R&D and may collaborate with various stakeholders during pharmaceutical R&D** (Figure 1).

During early research, **thousands of compounds could be candidates** for what will eventually become a single authorized medicine (**read Section 1.2. on bringing medicines and vaccines to the market for more details**). Following this phase, innovative pharmaceutical companies typically take most of the financial risk of advancing compounds from basic research through pre-clinical and clinical phases to develop products that will improve individual and public health outcomes. Pharmaceutical companies usually fund late-stage clinical development, often the most expensive phase of R&D. **Phase III clinical trials** may correspond to nearly 27% of companies' R&D budget (**read Section 1.3. on R&D expenditure for more details**). Phase III clinical trials test the safety and efficacy of a compound in a large and diverse population pool, which may involve hundreds to thousands of patients at multiple sites globally. These trials are more cost-intensive and complicated than earlier phases of drug development and need to generate evidence in appropriate quantity and quality to meet regulatory standards.

Pharmaceutical companies are involved in all R&D stages and may collaborate with various stakeholders.

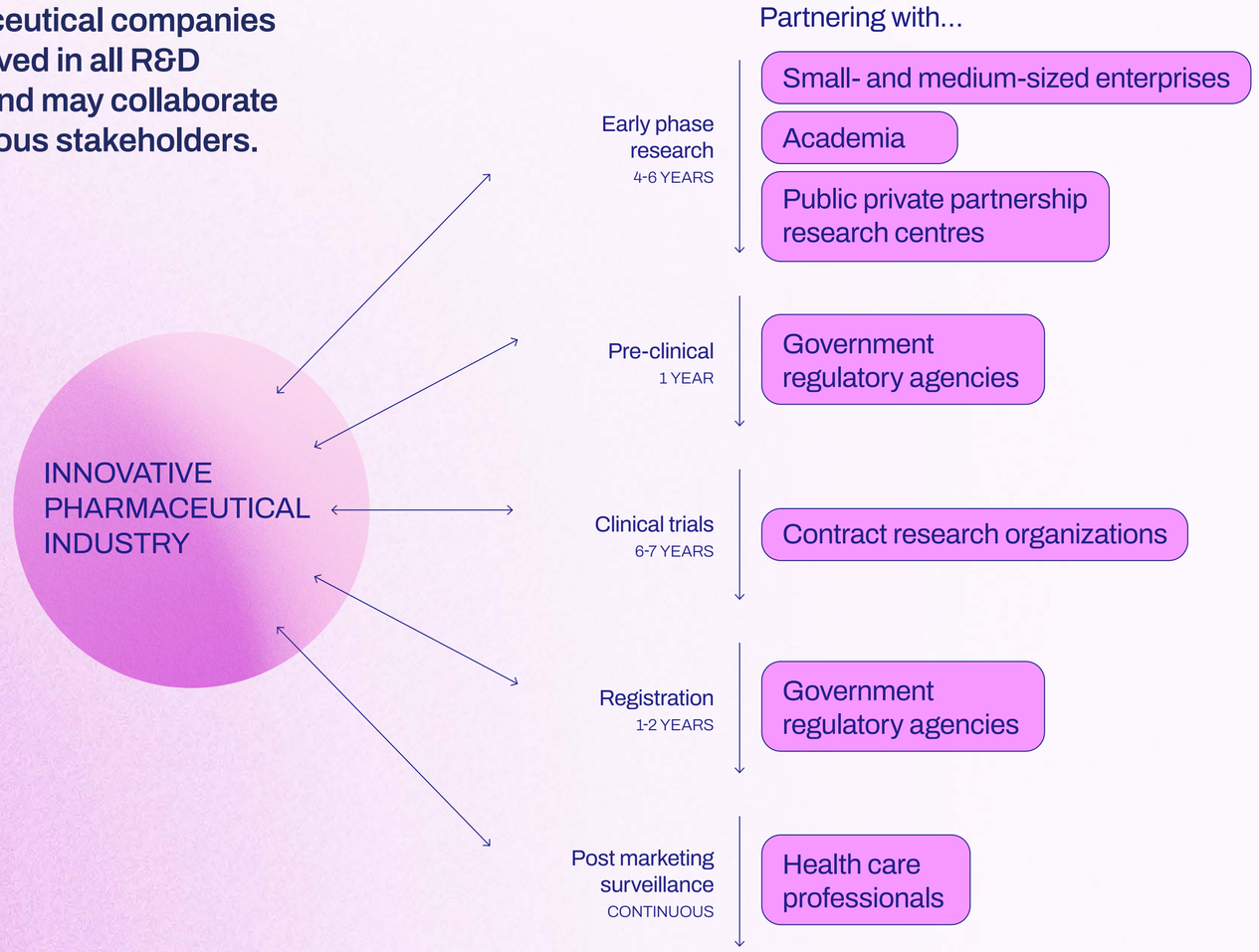
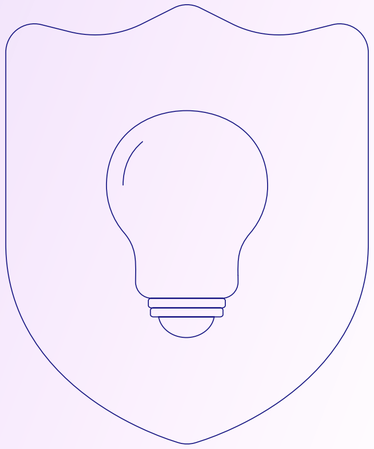


Figure 1: The pharmaceutical innovation process

Source: IFPMA Facts and Figures, 2022[3]



1.1.2
Intellectual property rights

Intellectual property rights (IPRs) play a crucial role in protecting inventions and incentivizing the high-risk R&D investments that drive pharmaceutical innovations. IPRs sustain an innovation ecosystem based on stability, certainty, and predictability of rules, in which innovators are incentivized to embark on the complex journey of pharmaceutical R&D. Relevant IPRs include patents, trademarks, copyright, trade secrets, designs, and Regulatory Data Protection (RDP).

Patents, a specific type of IPR, are granted upon disclosure of an invention that has fulfilled various conditions, including novelty, non-obviousness and industrial application (the invention must be capable of being used for an industrial or business purpose, or be useful).[4, 5] During the term of protection, the inventor (or owner of the invention) has the right to exclude others from commercially exploiting the invention.[4, 5] The patent applicant must disclose the invention to obtain protection, allowing others to access new knowledge.[4] The inventor (or owner of the invention) can also "**license a patent,**" granting permission to another individual/organization to make, use, and sell the patented invention, in accordance to agreed terms and conditions.[5] This is often done through voluntary licensing and could include technology transfer. Once a patent expires, the invention enters the public domain[4] and the patent holder loses his rights to the invention.

In 2022, the pharmaceutical industry submitted 12,425 patent applications via the Patent Cooperation Treaty administered by the World Intellectual Property Organization (WIPO), underscoring its efforts to bring innovations to society.[6] **While patents protect inventions, RDP (or data exclusivity) protects data.** RDP provides a limited duration of time during which only the owner, or generator, of preclinical and clinical trial data can use it to obtain marketing authorization.[7] The duration of these rights is based on national legislation. To secure marketing approval, companies need to provide to NRAs extensive data to attest a medicine's safety, efficacy, and quality.[8] RDP protects the investments needed to generate this extensive body of data, incentivizing pharmaceutical companies to make significant R&D investments.[9] Only after the RDP period, generics can rely upon the originator product's data to obtain marketing authorization for their products.[9]

Allowing continuous research

IPRs facilitate scientific progress through knowledge sharing. For a patent to be granted, the inventor must publicly disclose information on the invention to the public.[4] This information enriches collective scientific and technical knowledge and may encourage further innovation by other stakeholders such as companies, academic institutions, or research institutions.

Enabling partnerships

The intellectual property (IP) framework enables the industry to collaborate and partner with other stakeholders of the innovation ecosystem, such as academia, biotechs, and research laboratories.

The IP framework enables collaborators to form partnerships on a voluntary basis and on mutually agreed terms. This is important because pharmaceutical companies differ from one another. Each company may have specific capabilities, expertise, experience, ability to scale up manufacturing, and track record. All these factors may influence, for instance, how viable a company is to receive a technology transfer (**read Section 3.4. for more details on technology transfers**).

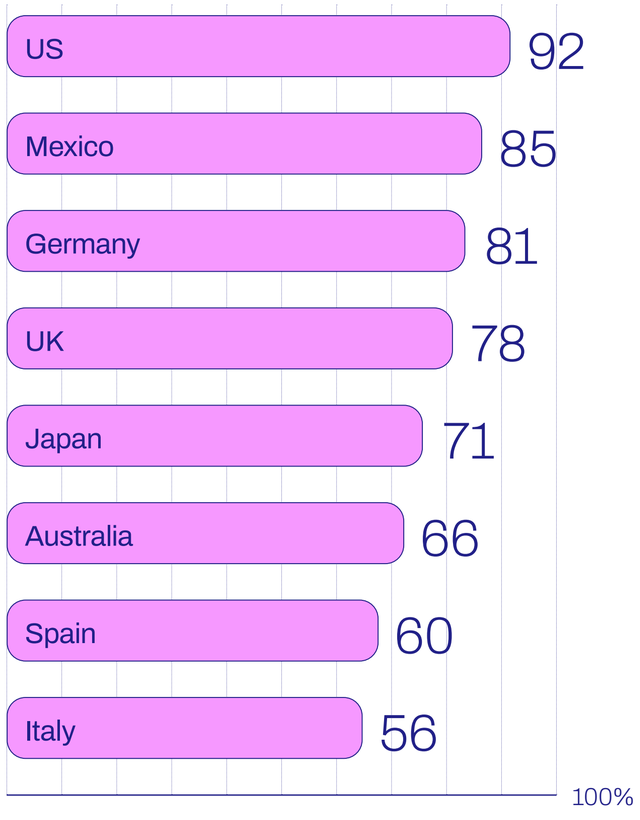


Figure 2: Approximate share of volume of generics (including brand-name non-originators and unbranded generics) by country

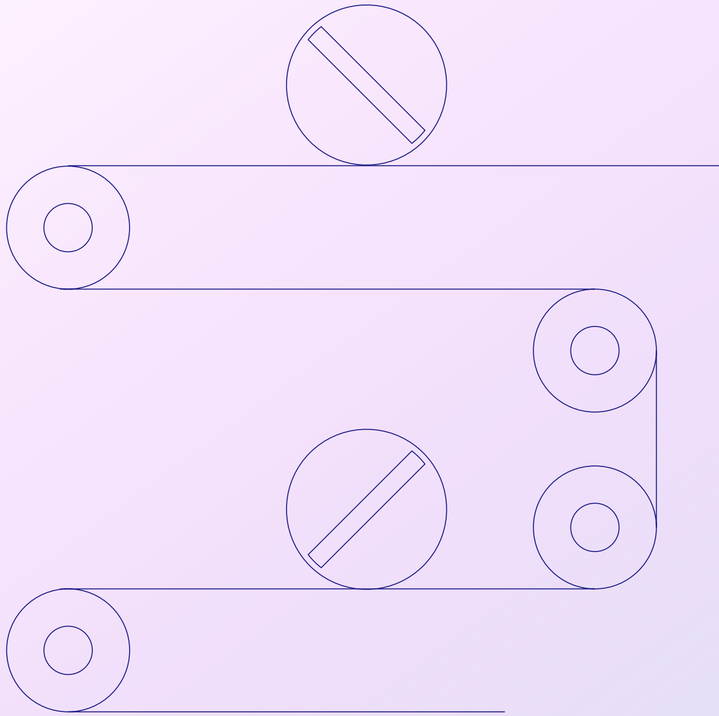
Notes: data derives from analysis of 2022 sales and volume data, undated (run date May 19, 2023).

Source: Department of Health and Human Services, 2024[10]

1.1.3 Relation between innovative products and generics

In addition to catalyzing innovation, the predictability of the IP framework ensures that companies producing generics or biosimilars have a continued pipeline for production. Generics and biosimilars are widely utilized in healthcare systems globally. Generic versions of IPR protected medicines and vaccines, under a license, or those off IPR protections may be more affordable than IPR protected medicines. This is because generic companies do not need to recoup high development costs. Generics account for most drug volume in some of the largest markets globally. In the United States (US), the volume penetration of generics was more than 90% in 2019 (Figure 2).[10] Generics and biosimilars could not be produced without the solid IP protections that encourage the development of medical breakthroughs in the first place.

Every two years, the World Health Organization (WHO) publishes its List of Essential Medicines Model List of Essential Medicines (EML), which includes “medicines deemed essential for addressing the most important public health needs globally”.[11] As of January 2022, almost 93% of the items (442 out of 477) listed on the 22nd edition of the EML were medicines not patented in low- and middle-income countries (LMICs).[11]



1.2 Bringing medicines and vaccines to market

1.2.1 Embarking on a complex process

Innovative medicines and vaccines offer new ways to prevent, treat, or cure diseases. This improves the lives of people and allows individuals to be active in society and contribute to economic prosperity. But **developing new medicines and vaccines is a complex, costly, and lengthy process in which success is not assured**. Many potential candidates progress for several years, but still end up failing at different development stages.[12] Unsurprisingly, medicine R&D is considered one of the most financially risky endeavours in science.[13]

Key stages of medical product development involve early discovery, preclinical research, clinical research, and regulatory evaluation (Figure 3).[3, 14] Following regulatory approval, post-market safety surveillance is conducted to explore continued safety and treatment benefits in the general population.

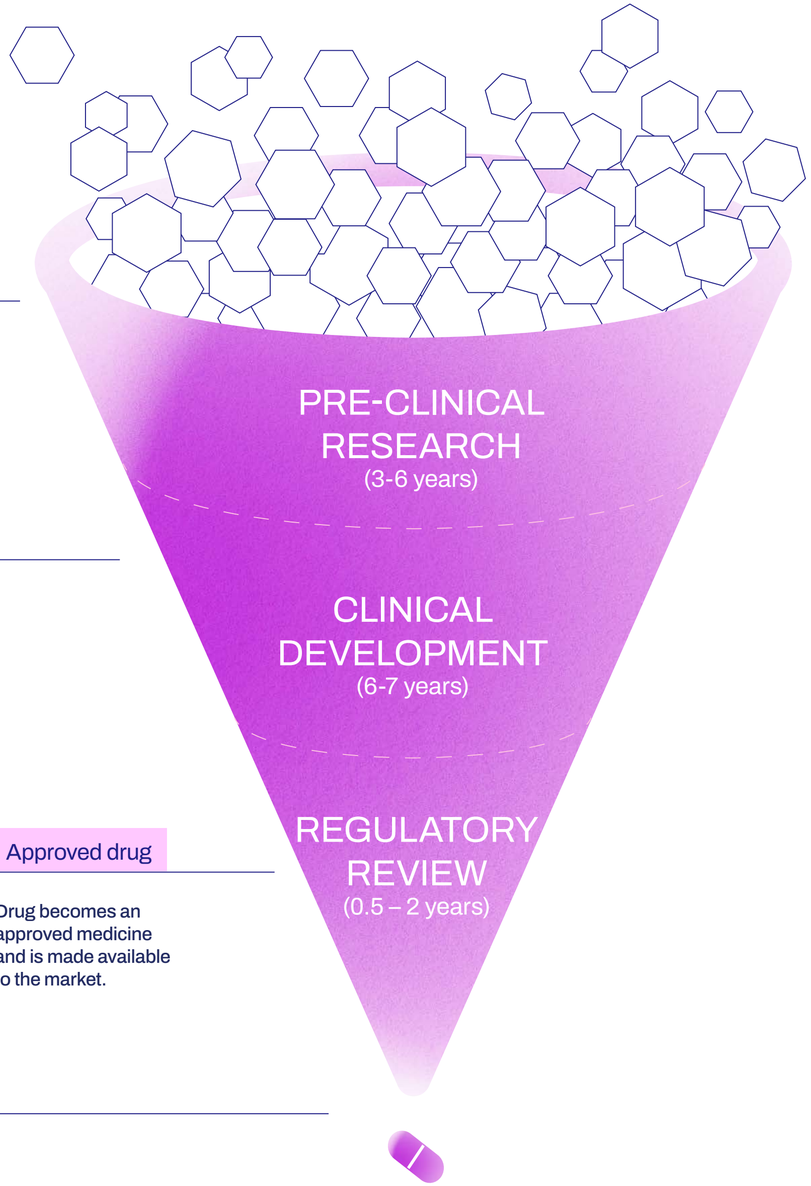


Figure 3: The R&D process

Source: IFPMA[3], Pugatch Consilium[14]

On average, **one or two out of every 10,000 (0.01% or 0.02%) compounds** synthesized in laboratories successfully pass all development stages required to enter the market.[12] A compound needs to be extensively and rigorously tested during clinical trials to ensure its efficacy and safety, part of a process that **can take 10 to 15 years** for both a medicine and a vaccine.[15] When entering Phase I clinical trials, drug candidates have only a **10% probability of market entry.**[15] On average, it costs **USD 2.6 billion to develop one new medicine**, considering the cost of failures.[16]

Notably, clinical trial enrollment durations (the time from trial start to enrollment close) have been increasing over the past five years across all phases and therapeutic areas. The average time from trial start to patient enrollment close for trials increased by 26% from 2019 to 2023 (Figure 4),[17] underscoring the growing complexity of pharmaceutical R&D.

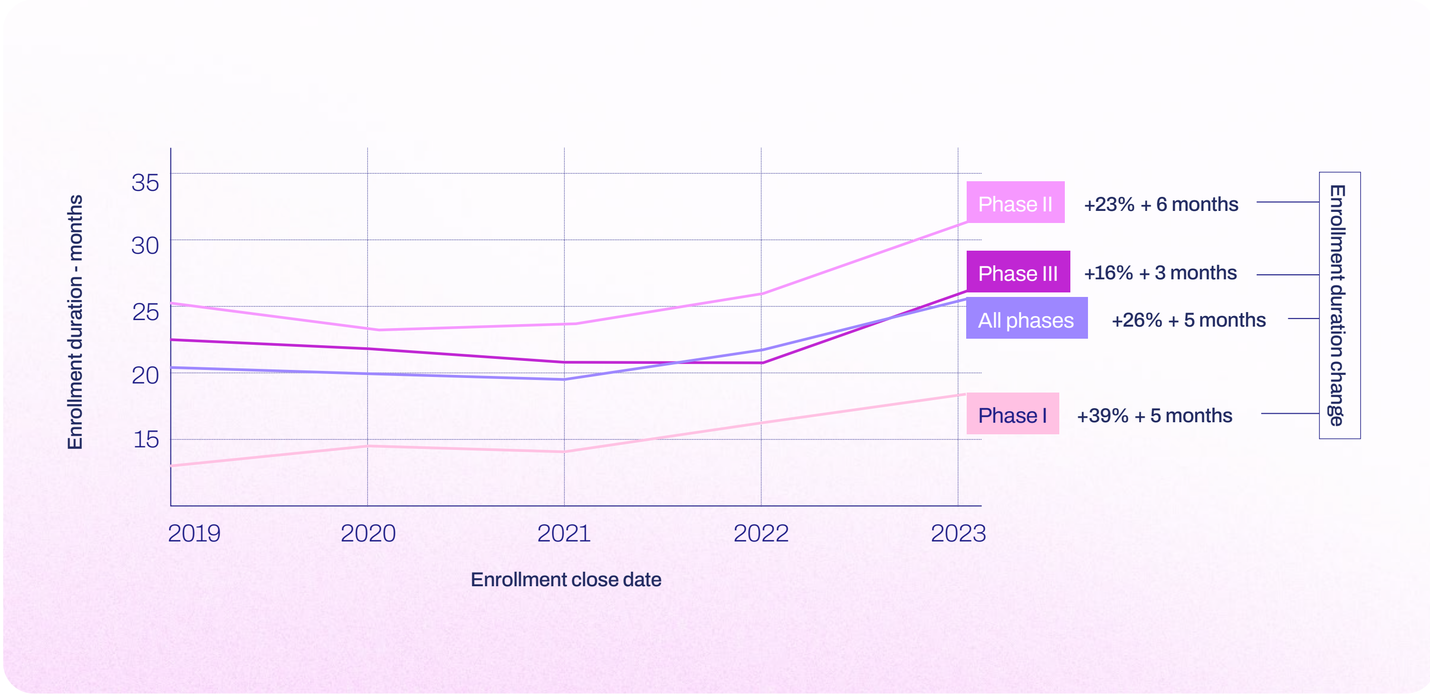


Figure 4: Enrollment duration in months by phase for all industry interventional clinical trials — by enrollment close date

Source: IQVIA, 2024[17]

The number of global commercial clinical trial starts (those sponsored by companies) grew by 38% over the last decade (Figure 5).[18] The share of commercial trial starts of the European Economic Area (EEA) declined from 22% (in 2013) to 12% (in 2023). The combined share of commercial trial starts in North America, EEA, and the rest of Europe declined from 64% in 2013 to 49% in 2023. On the other hand, the combined share of commercial trial starts of Asia and China grew, from 16% in 2013 to 33% in 2023; with China moving from 5% (in 2013) to 18% (in 2023). Finally, the US continues to be the largest single country for commercial clinical trial starts. Contributing to these trends is an increase in single country commercial trials in the US and China, so when considering multi-country commercial trials only, Europe's fall in global share appears less pronounced.[18]

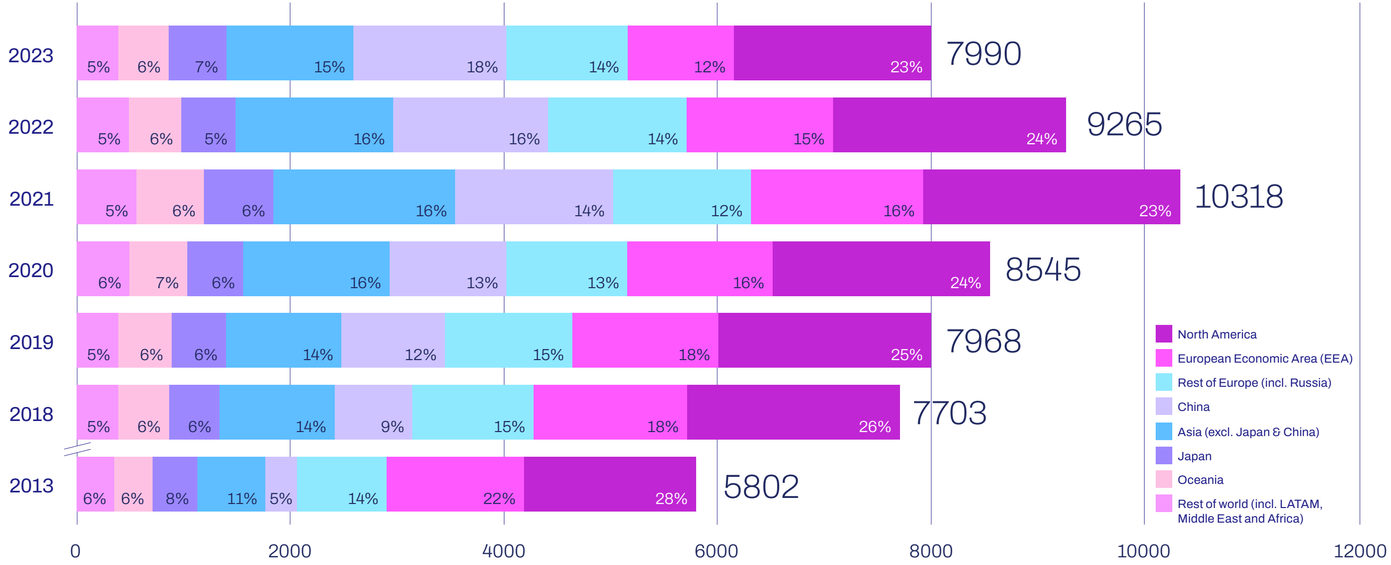


Figure 5: Number of global commercial clinical trial starts by region (2013, 2018 – 2023; Phase I-IV)

Note: Medical device trials and terminated/suspended trials were excluded. Trial with sites in multiple regions were counted once for each region.

Source: EFPIA, 2024[18]

Developing vaccines

Developing vaccines is associated with specific **clinical and logistical considerations**.[19] It is estimated that, from pre-clinical stage, vaccines have on average a 6% probability of market entry.[20] Evolving epidemiology, including the emergence or disappearance of variants, strains, and pathogens, can complicate the R&D process.[21] Vaccines are often preventive in nature, and, as a result, they are studied in healthy and very large populations. Large-scale phase III vaccines clinical trials can focus on studying safety and efficacy on thousands to tens of thousands of people.[22]

Manufacturing

During pharmaceutical R&D, companies also plan their **manufacturing, distribution, and scale up activities**. To bring a medicine to market, companies must be able to transition from manufacturing medicines in small experimental batches for clinical trials to manufacturing medicines in large quantities for those that need them.[23]

Companies invest significant resources into building manufacturing sites, managing complex supply chains, ensuring sufficient production capacity, maintaining quality standards of their plants or those of their licensees, and securing regulatory approvals for new manufacturing facilities. Managing manufacturing facilities is complex and building a new manufacturing facility can cost up to USD 2 billion and take 5 to 10 years.[24] It is estimated that most of the time needed for manufacturing (up to 70%) for vaccines is spent on quality control.[25, 26]

1.2.2
Many forms of innovation

Therapeutic progress is often achieved through multiple waves of innovation, with initial advances followed by incremental innovations or breakthrough innovations. For instance, in the 1980s, human immunodeficiency virus (HIV) was perceived as a death sentence.[27] Today, thanks to waves of scientific progress, people with HIV can live with it as a manageable, chronic condition.[28] Since the HIV virus was discovered, more than 30 medicines have been approved to treat the HIV infection and, with time, medicines improved in tolerability, efficacy, and convenience for patients.[28] For instance, the approval of the first antiretroviral therapy (ART) in 1987 was followed by the Highly Active Antiretroviral Therapy (HAART) combination approach, which inaugurated a new era in HIV treatment. These accomplishments were succeeded by the approval of Pre-Exposure Prophylaxis (PrEP), which has further transformed HIV prevention.[29] Moving forward, a twice-yearly injectable HIV-1 capsid inhibitor could be available for patients.[30]

Company R&D activities do not stop once a medicine receives marketing approval. Post-approval R&D – including clinical trials – can be undertaken to understand how a medicine can be further improved and explore potential additional benefits for different diseases, settings, and patient populations. For instance, a medicine approved for a specific indication can be approved for new indications or in combination with other medicines.[31] Post-approval R&D is responsible for much of the progress in the fight against cancer over the past decade. Most cancer medicines today are approved for multiple indications, with additional approvals received years after a medicine's first approval.[32]

Approvals for **new patient populations**, such as pediatric populations, are another important example of incremental innovation. Despite more than half of all children receiving at least one prescribed medication annually, relatively few medications have a pediatric formulation available.[33] Conducting pediatric clinical trials is particularly complex and requires careful consideration to guarantee the safety of this vulnerable population (with important demographic and physiological differences compared to adults). Thanks to continuous post-approval R&D efforts, several medicines initially approved for adults have later been approved for pediatric populations.

New formulations can facilitate storage via longer shelf-life or heat-stability or allow for extended-release formulations.[31] For instance, some formulations provide pain relief over a longer period and reduce the frequency of dosing needed for chronic pain management.

New dosage forms can be compatible with **new delivery methods**, and might allow, for instance, a move from intravenous infusion to self-administered injections.[31] Progress in diabetes technologies has improved patient ease of use and adherence, moving from a vial and syringe for injecting insulin to insulin pens, insulin pumps, and sensor-augmented pumps.[34]

1.3 R&D intensity and investment

With an R&D intensity[i] of 30%, the pharmaceutical industry invests substantially more in R&D, compared to other R&D-intensive industries among countries of the Organisation for Economic Co-operation and Development (OECD).[35]

Without pharmaceutical R&D investments, the continuous development of new medicines and vaccines that improve quality of life for individuals would not be possible, nor would the subsequent predictable production of generics and biosimilars of these medicines. Pharmaceutical companies heavily invest in R&D at global scale, with estimates suggesting that global pharmaceutical R&D spending in 2021 reached USD 276 billion across 4,191 companies around the globe, with total net revenue of USD 1,022 billion across 583 companies. This indicates that the global pharmaceutical industry spends 27%[ii] of its revenue on R&D.[36]

Separate analysis looks at the broader healthcare sector (pharmaceuticals, biotechnology, medical equipment, healthcare equipment and services, healthcare providers and medical supplies), within a panel of 2,500 top companies worldwide in 2022, R&D expenditure constitutes 12.9% of their total revenue in R&D[iii].[37]

The **top 50 pharmaceutical companies alone are estimated to have spent a total of USD 167 billion in R&D in 2022** (Figure 7).[38] R&D spending of the top 50 pharmaceutical companies has been rising, increasing by almost 60% in the 10 years from 2012 to 2022. The projected annual increase in R&D spending is set at 6.7% with annual estimated expenditure predicted to cross USD 200 billion by 2025.[38]

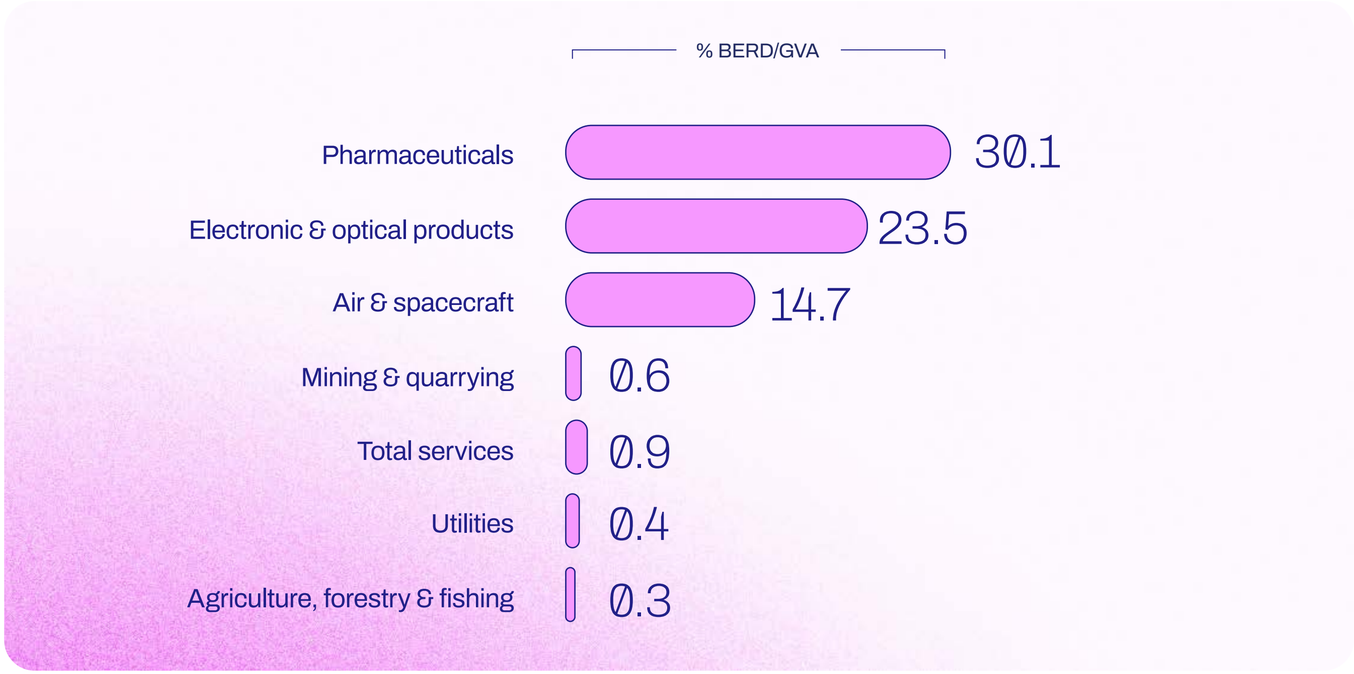


Figure 6: R&D intensity by industry (business enterprise expenditure on R&D as a share of gross value added), 2019 or nearest year*

* Business enterprise expenditure on R&D (BERD) includes R&D by corporations regardless of source of funding. Data are based on the 17 OECD countries for which information is available for the Air & Spacecraft category, and on the 31-34 countries for all other industries.

Source: OECD, 2023[35]

i R&D intensity calculated as business enterprise expenditure on R&D as a share of gross value added.
ii R&D expenditure as a percentage of sales.
iii Health industries share of global R&D expenditure.

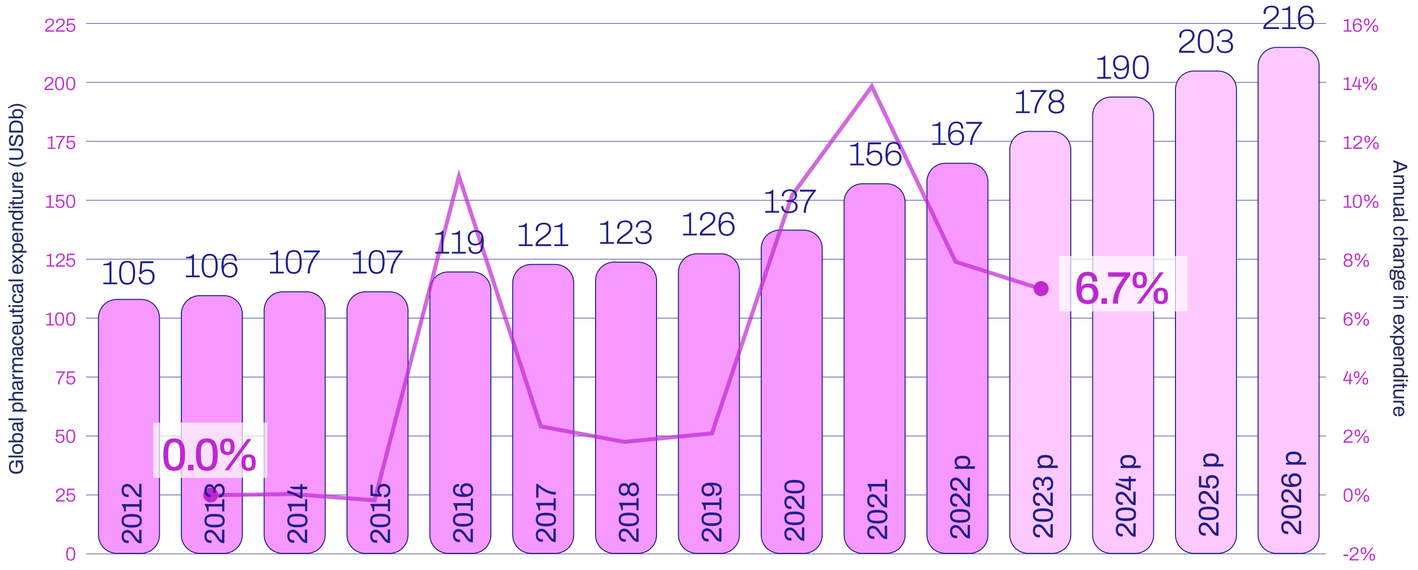


Figure 7: Estimated R&D expenditure of the top 50 pharmaceutical companies (2012-2026p)

Notes: * p – Projected figures were calculated based on an average annual growth in Research & Development expenditure between 2018 and 2022 (6.7%)

Source: Centre for Medical research (CMR), Clarivate, 2024[38]

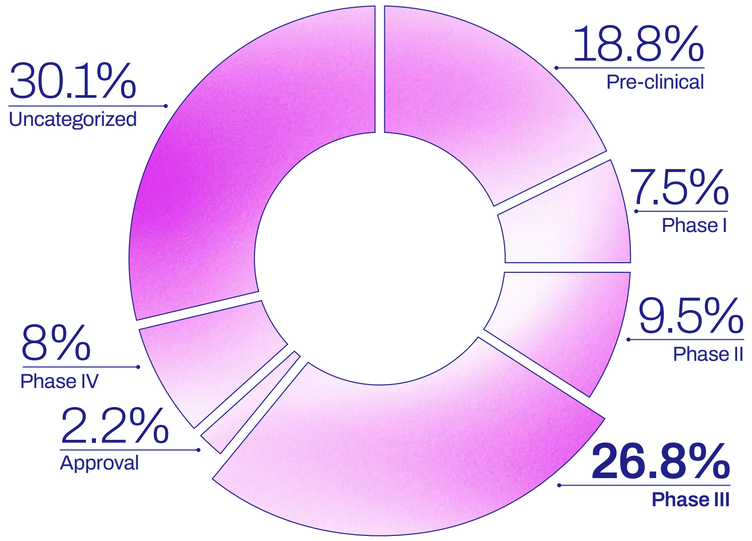


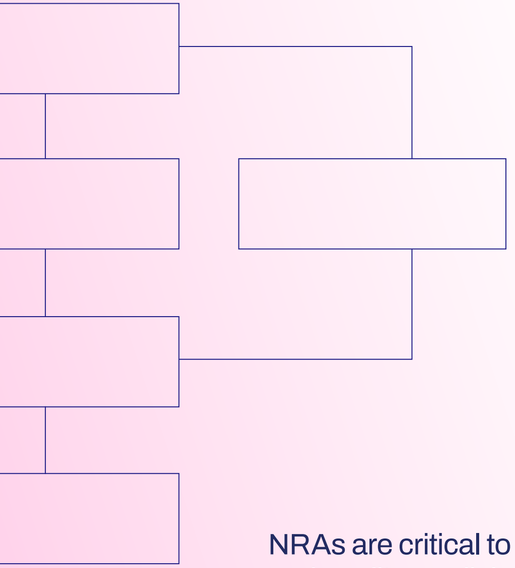
Figure 8: Companies' approximate share of R&D by function, 2022

Notes: Data based on results from a PhRMA Member Companies survey in 2023
All figures include company-financed R&D only. Total values may be affected by rounding.

Source: PhRMA, 2024[42]

Clinical trials are often responsible for most of the R&D expenditure of pharmaceutical companies, accounting for about half of their total R&D costs.[39] Drivers of clinical trial costs include patient recruitment, site recruitment and retention, patient retention and engagement, and data management and validation.[40] While the use of artificial intelligence (AI) may offer new opportunities to boost R&D efficiency, clinical trial requirements, regulatory changes, and the impact of inflation are contributing to high R&D costs, placing pressures on the pharmaceutical R&D operating model.[41] Phase III clinical trials are particularly expensive for pharmaceutical companies, and may account for roughly 27% of their R&D (Figure 8).[42]

1.4 Different and evolving regulatory frameworks



NRAs are critical to ensuring that safe, effective, and quality medicines and vaccines are available for people.[2] Despite pharmaceutical R&D increasingly being a global activity, **countries have different regulatory frameworks**. Global pharmaceutical companies must carefully consider this complex landscape of regulatory frameworks when developing medicines, planning clinical trials, and presenting data to NRAs for their regulatory evaluations.

Strengthening regulatory frameworks and harmonizing requirements

Regulatory frameworks vary across jurisdictions, with the World Health Organization (WHO) highlighting that less than 30% of NRAs globally are believed to have the capacity to ensure that medicines, vaccines, and other health products are safe, effective, and quality-assured.[43] **Efforts are being taken to strengthen regulatory systems, particularly in low- and middle-income countries (LMICs).**

For example, the African Medicines Agency (AMA) aims to create an enabling regulatory environment for medicines in Africa.[44] The AMA was adopted by the African Union in 2019 and 26 countries had ratified it by July 2024.[45] The operationalization of the AMA is likely to strengthen regulatory capability and capacity, possibly leading to timelier access to safe, quality, and efficacious medicines and vaccines for African people.[46] In LMICs, scarce resources and insufficient regulatory capabilities can make it difficult to identify and stop the market entry of falsified medicines.[47] The circulation of falsified and substandard medicines is a major issue in the African continent[48] and the AMA is expected to help to improve patient outcomes and safeguard against the use of falsified and substandard medicines across African health systems.[46]

Efforts are also being taken to increase **harmonization and convergence of international regulatory standards**. For instance, the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) provides a unique platform for industry and regulators to harmonize regulatory requirements, reduce duplication of efforts, and offer consistent standards globally.[49, 50]

Regulatory agilities

Regulatory agility is important to make innovations available to patients in a timely manner. During the COVID-19 pandemic, NRAs allowed and implemented various regulatory agilities to ensure speedy patient access to much-needed vaccines and medicines to tackle the pandemic. Key agilities included **accelerated reviews, digitalization of methods** (such as decentralized clinical trials and remote inspections), and the use of **regulatory reliance** to facilitate the rapid approval of products. Moving forward, thanks to this experience, NRAs may be more comfortable implementing regulatory agilities as they deem appropriate.

Today, regulatory reliance is recognized as a useful and efficient regulatory tool.[51] Reliance in decision-making offers a pathway for NRAs to consider evaluations conducted by other NRAs while maintaining accountability for their decisions. By avoiding duplicative reviews and optimizing resource allocation, the use of regulatory reliance can lead to faster patient access to safe and effective medicines.[51]

Regulatory agility is important to make innovations available to patients in a timely manner.

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Advancing innovation

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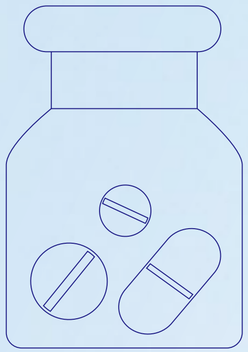
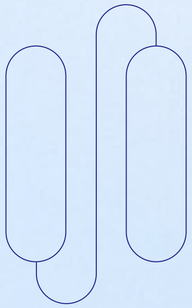
KEY FACTS AND FIGURES

Advancing innovation



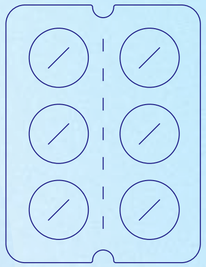
69

In 2023, **69 novel active substances (NASs)** were launched globally, six more than the previous year.



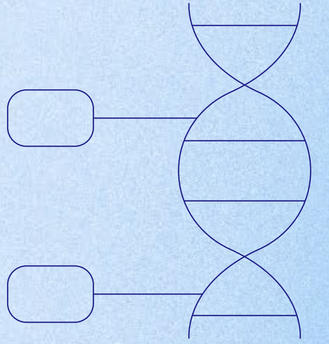
6

As of August 2024, the Food and Drug Administration (FDA) of the United States had approved **six CAR-T products**.



942

In the past 20 years (2004-2023), **942 novel active substances (NASs)** have launched globally, targeting various disease areas, such as oncology, neurology, and infectious diseases.



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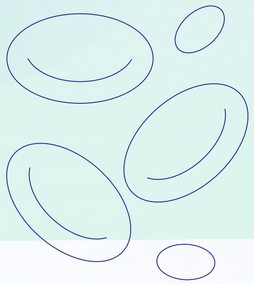
Six first-in-class cell and gene therapies were launched in 2023, including one for Duchenne muscular dystrophy (DMD) and one for Hemophilia A.

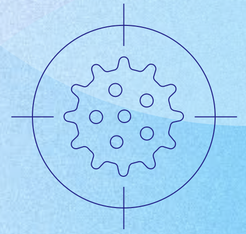


3x

Over the past 10 years, industry-sponsored trials for cell and gene therapy have **more than tripled**.

285

There were over **285 vaccines** (preventive or therapeutic) under development by companies, as of July 2024, either in clinical trials or awaiting review of the Food and Drug Administration (FDA) of the United States.



12,700

As of October 2024, there were over **12,700** medicines at different phases of clinical development globally, supported by the pharmaceutical industry, biotechs, academia and medical research charities.

2. Advancing innovation

2. Advancing innovation

Substantial efforts in high-risk R&D continue to drive pharmaceutical innovation and over 69 novel active substances (NASs)[iv] were launched globally in 2023. The global pipeline for medicines and vaccines is comprised of thousands of compounds at different stages of development, tackling multiple disease areas. Over the years, pharmaceutical advances have transformed diseases once considered deadly into manageable or even curable conditions today.

Recent pharmaceutical innovation has led to breakthroughs in Alzheimer's disease, obesity management, cancer treatment, curative and disease-modifying gene therapy, gene editing, and vaccine development. Looking ahead, the rise of Artificial Intelligence (AI) and Machine Learning (ML), as well as advancements in biotherapeutic medicines, gene editing, and precision medicine, hold great promise to revolutionize healthcare.

iv Novel Active Substance (NAS) is defined by IQVIA as a medicine with at least one novel ingredient and that launches in a year for the first time in the relevant geography. Fixed-dose combinations are NAS if one of the ingredients is novel but would not be considered NAS if both are previously available alone or in other combinations. Emergency use authorizations are counted as NAS in the year the medicine became available to patients and no exclusion is applied for approval type. COVID-19 vaccines are counted as NAS based on which of the 8 subtypes of vaccine technology was used to create them. Launch of NAS in each geography are counted independently, meaning the totals for each geography include different products, and the global is a representation of distinct first global launches.

2.1 New medicines and vaccines

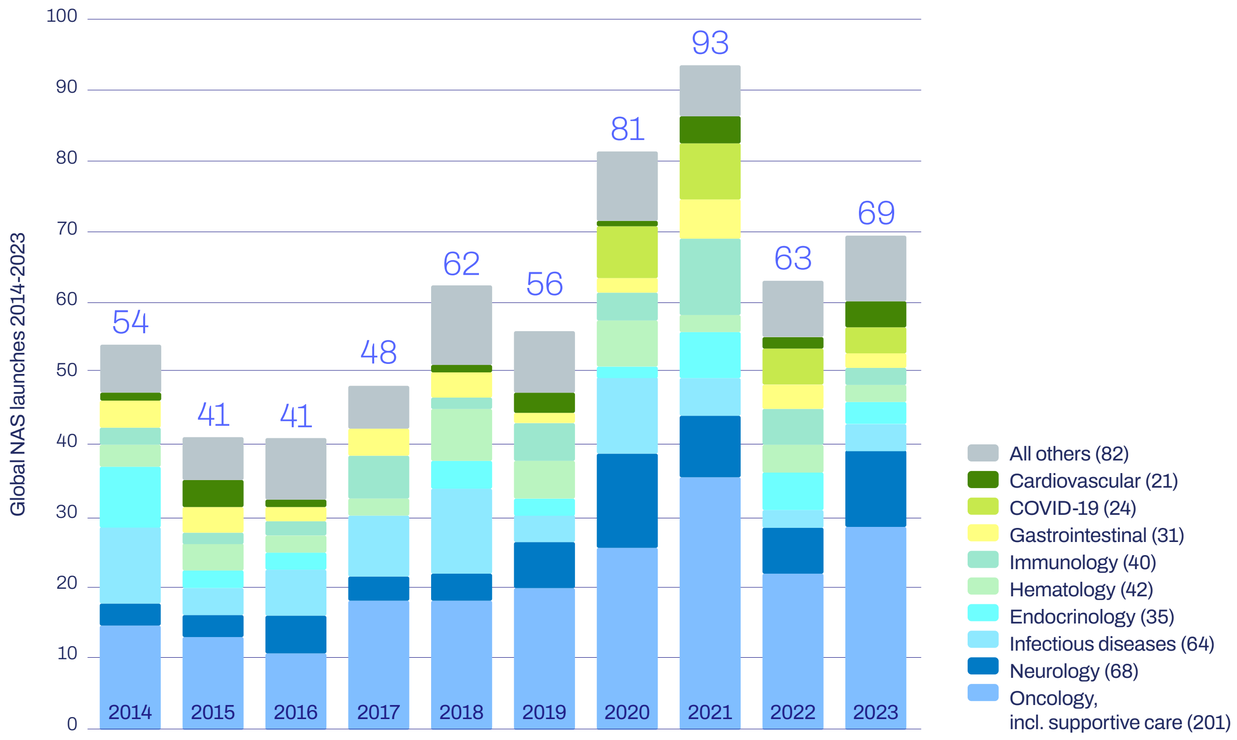


Figure 9: Global launches of novel active substances (NAS) by therapy area, 2014–2023

Abbreviation: NAS, novel active substance.
Definitions: A novel active substance (NAS) is a new molecular or biologic entity or combination where at least one element is new. Includes NASs launched anywhere in the world by year of first global launch. Launch is determined using IQVIA audits of sales activity as well as companies' public statements. Oncology includes supportive care & diagnostics. COVID-19 includes novel medicines only and does not include previously approved medicines with new approved uses for COVID-19. Please note: each NAS could be launched in multiple regions.

Source: IQVIA, 2024[52]

In the past 20 years (2004-2023), 942 novel active substances (NASs) were launched globally,[52] targeting various diseases like cancer, cardiovascular diseases, and infectious diseases such as HIV, Ebola, and smallpox. These achievements would not have been possible without a strong global framework protecting the IP that underpins these innovations.[53]

In 2023, 69 NASs were launched globally, six more than the previous year, including 24 first-in-class launches in the US. This marks a rise of 10% from 2022 and represents a return to pre-COVID-19 levels (Figure 8).[52]

From 2019 to 2023, 362 NASs were launched globally, with an increasing proportion attributed to oncology, neurology, and immunology launches (204 of the 362 launches (56%) compared with 105 of 246 (43%) over the previous five-year period of 2014 to 2018) (Figure 9).[52] In the last 10 years, the 201 oncology launches included cell and gene therapies (n=11), as well as innovative modalities like 12 antibody-drug conjugates and nine bispecific antibodies.[52]

Notably, infectious disease treatments for bacterial, viral, fungal, and parasitic pathogens include new launches for HIV, Ebola, and smallpox, and represent 11% of NAS launches over the last 10 years, with some year-to-year variability.[52]

Notwithstanding annual variability, an increasing trend in the number of global NAS launches can be seen during the last 20 years (2004–2023). In 2023, 57 NASs launched in the US, 33 in China, 22 in the four largest EU member countries (France, Germany, Italy, Spain) and the United Kingdom (UK), and 20 in Japan. Between 2019 and 2023, China was second only to the US in the number of NASs launched. While the US still has an absolute higher number of NASs launched compared to other regions, novel medicines are reaching China at an increasing pace (Figure 10).[52]

The outlook for molecules in the late-stage pipeline also looks promising, **with roughly 65–75 NASs expected to launch every year for the next five years**, bringing the total number of NASs launched globally to 325–375 by 2028.[52]

Despite the considerable advances in innovation and the new medicines and vaccines brought to market every year, unmet medical needs remain around the globe. For instance, more than 6,000 rare diseases still lack therapeutic options and various cancers (such as pancreatic cancers, mesotheliomas, and brain cancers) have a 5-year survival rate of less than 35%, underscoring the need for continued R&D efforts.[54]

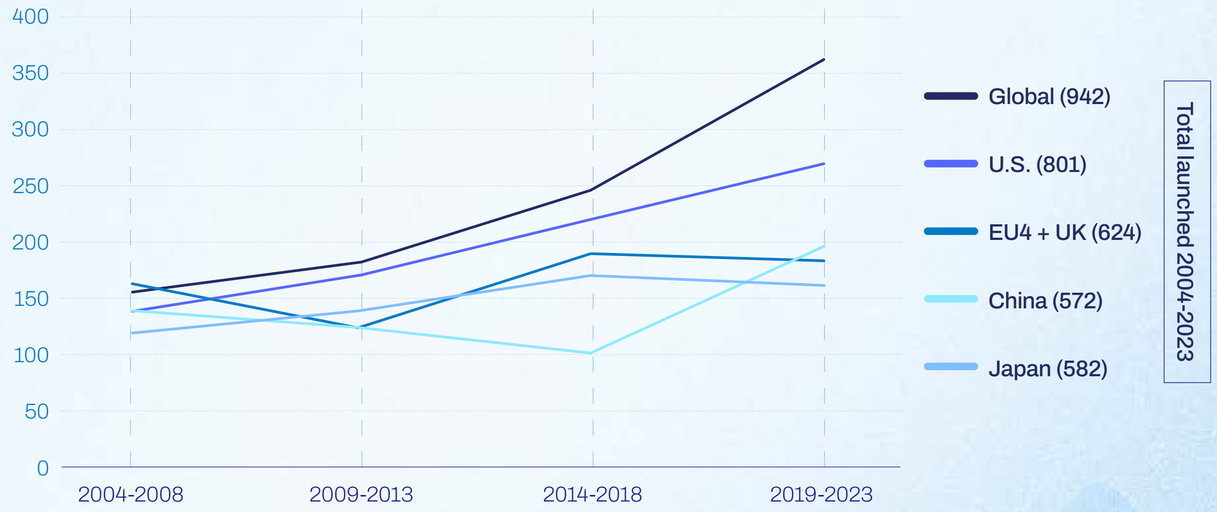


Figure 10: Number of NASs launched globally and in selected countries, 2004–2023

Abbreviations: EU4, France, Germany, Italy, Spain; NAS, novel active substance.

Source: IQVIA, 2024[52]

2.2 The R&D pipeline

2.2.1 Insights on the global R&D pipeline

The global R&D pipeline, significantly supported by the pharmaceutical industry, holds great potential to continue to address unmet medical needs, offering opportunities to advance treatments and prevention for various conditions and improve peoples' quality of life.

There are over 12,700 drugs[v] at different phases of clinical development[vi] globally.[55] Among these, approximately 1,200 are gene therapies. Furthermore, approximately half of the 12,700 drugs are biologics and the other half are small molecules.[55]

Most drugs focus on disease areas associated with high-mortality and/or high-burden, such as cancer (Figure 11).[55] For instance, based on projected changes in population growth and aging, and considering cancer rates remain unchanged, a 2024 report estimates that the number of new cancer cases will reach over 35 million by 2050, a 77% rise from 2022.[56] This means that roughly one in five people will develop cancer during their lifetime.[55, 56]

Most medicines (86%) are either in Phase I or Phase II, while only 14% are in Phase III (Figure 12).[55] This underscores the difficulties of advancing to Phase III clinical trials, which test a product's safety and efficacy in large patient populations and are aimed at generating substantial and high-quality evidence to meet strict standards of NRAs.

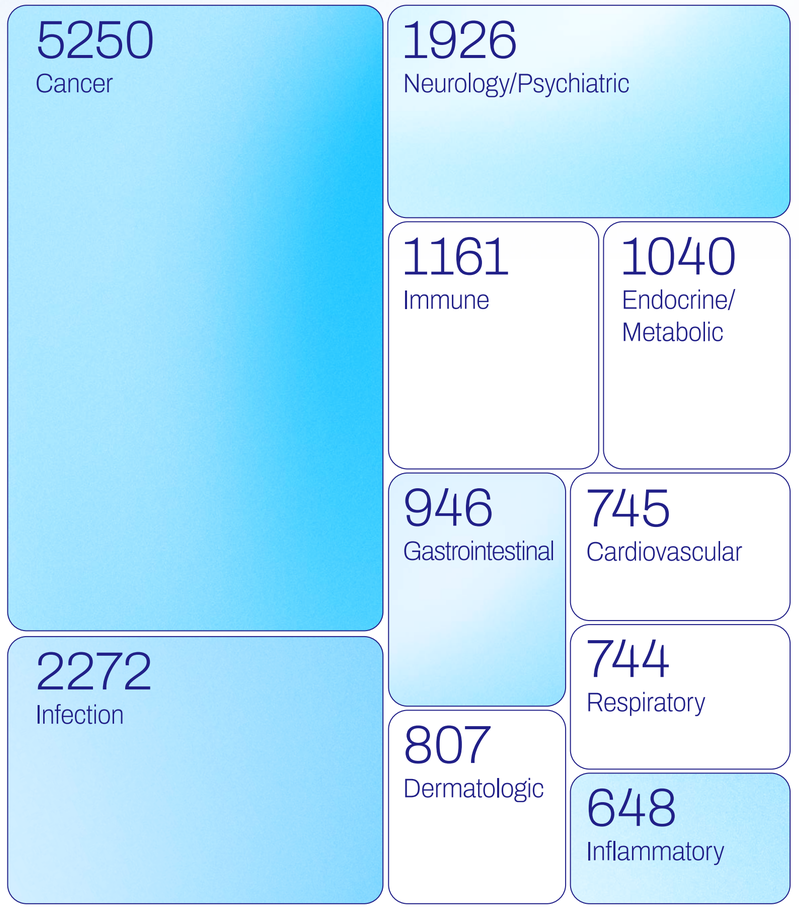


Figure 11: Top 10 therapy areas

Source: Data extracted on the 17th October 2024 from the Cortellis Competitive Intelligence database[55]

v "Drugs", as defined in the Cortellis Competitive Intelligence database, may include small molecules, biologics, drug combinations, biosimilars, salts, and new versions of existing drugs with an element of innovation, like a new formulation.

vi Only the most advanced stage of development globally is reported for each drug (for instance, if a drug is being investigated in both Phase I and Phase III for different indications, it would only be reported once, as being in Phase III).

2.2.2
A focus on vaccines

Pharmaceutical companies strive to increase protection against a broad range of diseases and strains through the development of vaccines, including research to extend the duration of immunity, and develop vaccine formulations and administration methods that are more accessible, making vaccination easier for patients and healthcare systems.

Vaccine candidates may rely on a variety of technology platforms. Depending on the target pathogen, various technology platforms can be used to create a vaccine.[57] This includes traditional platforms (such as live-attenuated vaccines and inactivated vaccines) as well as innovative platforms such as viral vector vaccines, nucleic acid vaccines (including messenger ribonucleic acid [mRNA] vaccines), and deoxyribonucleic acid [DNA] vaccines.[57] The ability to rely on **diverse vaccine platforms** is important to target different diseases, combat different pathogens, and strengthen the R&D pipeline.

PhRMA reported that, as of July 2024, there were **over 285 vaccines under development by companies, either in clinical trials or awaiting US FDA review.**[19] Vaccines in development include preventive vaccines that help to build immunity to diseases, and therapeutic vaccines, designed to fight diseases that a person already has, such as a cancer. Vaccines are being investigated to treat or prevent tropical/infectious diseases, cancers (including brain, skin, lung, and breast cancers), allergies, and even Alzheimer's disease.[58]

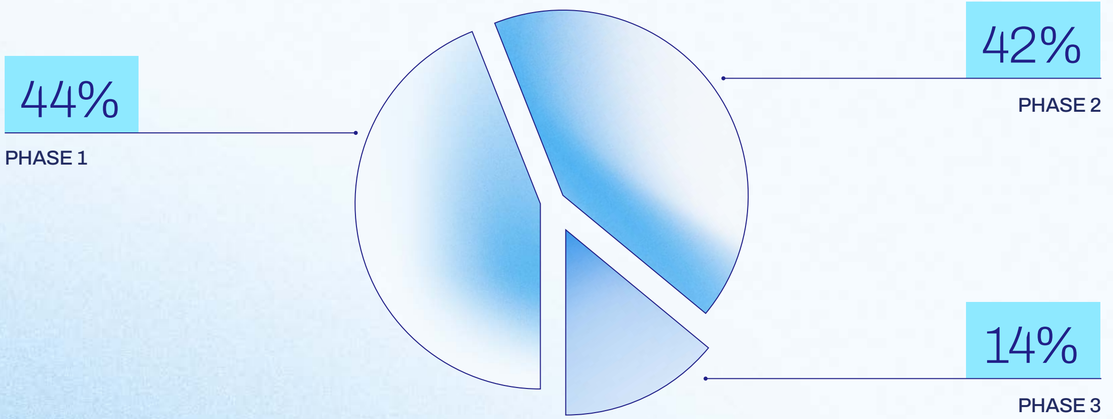


Figure 12: Percentage of drugs (total= ~12,700) per clinical trial phase, October 2024

Source: Data extracted on the 17th October 2024 from the Cortellis Competitive Intelligence database[55]

In recent years, progress in the vaccine pipeline has resulted in significant achievements in vaccine development. For instance, the US FDA approved the first vaccine to prevent dengue fever in 2019;[59] two respiratory syncytial virus (RSV) vaccines, the first one in 2023[60] and the second one in 2024;[61] the first vaccine against the chikungunya virus in 2023.[62] The first US FDA-approved Ebola vaccine was in 2019[63] and in late 2021, this vaccine helped control an Ebola outbreak in the Democratic Republic of Congo, limiting it to 11 cases compared to up to 29,000 cases in pre-vaccine outbreaks.[64] The European Medicines Agency also approved a second two-dose vaccine regime for Ebola in 2020.[65] Other key achievements include the WHO prequalification of two malaria vaccines (the first one in 2022 and the second one in 2023),[66] two dengue vaccines (the first one in 2020 and the second one in 2024)[66] as well as the prequalification of the first mpox vaccine in September 2024.[67]

2.2.3
Gaps in the R&D pipeline

Despite promising trends in the global R&D pipeline, some gaps remain, and the pipeline is considered insufficient for products tackling pathogens with pandemic potential, for new antibiotics, and for products tackling diseases disproportionally affecting LMICs.

Pathogens with pandemic potential

Building on the collaborative efforts that led to the development of diagnostics, drugs, and vaccines for COVID-19, in June 2021, G7 leaders welcomed the "100 Days Mission".[68] In this landmark collaboration, life sciences industry leaders joined forces with governments to step up collective efforts to save lives and tackle global pandemics, with a new commitment for partnership working to achieve better pandemic preparedness.[69] The mission aims to ensure readiness to produce diagnostics, therapeutics, and vaccines (DTVs) that enable the most efficient and equitable response possible to pandemics. According to the 2023 100 Days Mission implementation report, changes needed to achieve the ambitious 100 Day target across the development pathway – including in clinical trials and regulatory processes – are progressing slowly and the **early-stage therapeutics R&D pipeline for pathogens of pandemic potential remains very limited**.[70]

Furthermore, INTREPID Alliance is a consortium of innovative pharmaceutical companies that aims to accelerate antiviral treatments pipeline ahead of future pandemics,[71] bringing together the expertise of its members to help prioritize promising assets in the pipeline, support their advancement, and catalyze new partnerships to fill potential gaps. INTREPID leadership participated in the launch of the 100 Days Mission Therapeutics Roadmap by the International Pandemic Preparedness Secretariat (IPPS). INTREPID has analyzed key antiviral compounds under investigation, providing useful data in support of the 100 Days Mission. In October 2024, INTREPID published its Antiviral Clinical and Preclinical Development Landscape adding a list of preclinical antiviral compounds to its ongoing analysis of clinical antiviral compounds in development, targeting the 13 viral families identified with the biggest pandemic potential,[72] highlighting significant R&D gaps that need to be overcome.

Encouraging R&D to help protect against pathogens, such as SARS-CoV-2, which infect humans for the first time causing an outbreak or pandemic is challenging due to the lack of economic rationale for the investment – there is no market before the outbreak and there aren't other incentives. New incentives will be needed to attract public and private researchers to work in this area.

New antibiotics

With the rise of antimicrobial resistance (AMR), it is crucial to have an R&D pipeline that can deliver new antibiotics to treat patients with infections resistant to existing antibiotics. However, the current antibiotic pipeline is insufficient to meet the demands of increasing resistance in key pathogens.[73] Since its release in 2017, the WHO Bacterial Priority Pathogens List (BPPL) has guided R&D investment and formed the basis for activities related to monitoring and controlling antibacterial resistance. The new 2024 BPPL expands on the 2017 list to address current challenges, offering guidance to different stakeholders, including policymakers and health authorities. It highlights 15 families of antibiotic-resistant pathogens, categorized as critical, high, or medium priority for R&D and public health measures.[74]

The incentives to invest in R&D for antibiotics are currently insufficient. Antibiotics should be used sparingly to maintain their effectiveness and slow down the emergence of resistance. Consequently, new antibiotics — essential when existing treatments fail — should only be used to treat patients with resistant infections. While imperative from a stewardship point of view, this factor limits sales volumes and reduces companies' economic return on antibiotic R&D. However, continued

innovation is crucial.[75] Despite warnings, bankruptcies of antibiotic biotech companies, the loss of experienced antibiotic researchers to other disease areas and the general acknowledgment that the pipeline is inadequate, government action in this space remains limited.[73] The UK conducted a successful pilot of an innovative subscription model for antibiotics and has now made it permanent.[73] Under the model, a fixed subscription fee is paid to a company on a yearly basis for access to new antibiotics and there should be no incentive to overuse or over sell antibiotics.[76] **Appropriately designed incentives can help companies invest in the development of new antibiotics**, and the UK example should be seen as a proof of concept for a novel win-win approach.

In a study published in April 2024, the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) analyzed how the antibiotic pipeline might evolve over the next decade.[73] If no new incentives are introduced to encourage investment into antibiotic R&D, the pipeline is expected to contain 26 treatments, only six of which will be in late development stages (Phase II and III).[73] If effective pull incentives are introduced in 2025, this number could rise to 72 candidate treatments – 41 in late development stages.[73] These results underscore the crucial role of incentives in attracting investment and revitalizing antibiotic R&D.

Responsible use of antibiotics, developing new ones, and better leveraging vaccines all plays a role in tackling AMR, which would ideally also require **coordinated actions from multiple stakeholders**. Among several initiatives, the **AMR Industry Alliance** is one of the biggest private sector coalitions providing solutions to this challenge.[77] According to a 2021–2023 survey of its members, the majority (79%, n=34) invested in R&D for AMR-relevant products and/or technologies during the survey timeframe.[78] The industry-led **AMR Action Fund** is another vehicle that accelerates antibiotics R&D through investment and provision of resources and expertise to companies.[79] With its investments, the AMR Action Fund is working to bridge the funding gap between the discovery of antibiotics and patients. However, this additional funding is only a short-term solution and longer-term policy changes are needed to incentivize continued investment into the development of new antibiotics.

Products for diseases disproportionally affecting LMICs

Revolutionary products (including medicines and vaccines, but also diagnostics) have contributed to reducing the global burden of diseases disproportionally affecting LMICs over the past 20 years.[80] Between 1994 and 2022, an estimated USD 97.9 billion was invested in R&D for diseases disproportionately affecting LMICs, for basic research, drugs, diagnostics, vaccines, biologics, microbicides, and vector control products.[80] Given the limited economic incentives to invest in these disease areas, forming partnerships and implementing a mix of incentives can help to stimulate R&D and strengthen the pipeline.

A 2024 study from Impact Global Health (previously “Policy Cures Research”) highlighted that **every USD 1 invested in R&D for diseases disproportionally affecting LMICs** (including, but not limited to, vaccines and treatments) **generates a return of USD 405**.[80] The report also highlights that vaccines are still needed for 11 of the 15 disease areas mostly affecting LMICs, including HIV/acquired immune deficiency syndrome (AIDS), tuberculosis (TB), and rheumatic fever.[80] The number of approved medicines for diseases disproportionally affecting LMICs (n=51) is more than triple that of approved vaccines (n=16), with most disease groups having at least one approved medicine, but only four having approved vaccines. Figure 13 outlines the number of medicines and vaccines approved from 2020–2024 for 12 diseases primarily affecting LMICs (Figure 13).[80]

As of August 2023, the pipeline for diseases disproportionally affecting LMICs included 41 medicines and 65 vaccine candidates for malaria – a 55% increase in malaria vaccine candidates from 2019 (n= 42).[80, 81] There were also 56 vaccine and 23 biologics candidates for HIV/AIDS, and 20 vaccines and 55 medicines candidates for TB.[81] Pharmaceutical advancements can drastically reduce the burden of diseases disproportionally affecting LMICs. For instance, a recent WHO analysis estimated that a TB vaccine for adolescents and adults could avert on average 37.2–76.0 million cases and 4.6–8.5 million deaths by 2050; and that a vaccine for infants could avert 5.8–18.8 million cases and 0.8–2.6 million deaths.[82] The Global Plan to End TB 2023-2030 estimates that an annual investment of USD 1.25 billion in TB vaccine R&D is needed to end TB as a global health challenge.[83] These targets aim to reduce TB deaths by 90% and new cases by 80% by 2030, compared to 2015 levels.[83] There are currently hopes for the M72/AS01E vaccine candidate for TB (in Phase III) to potentially be the first new TB vaccine in 100 years if proven effective.[84]

Progress to develop medicines and vaccines for diseases disproportionally affecting LMICs is being made, including via product development partnerships (PDPs), which can drive R&D in areas of unmet need with low economic incentives by fostering collaboration among stakeholders such as academia, governments, industry, and philanthropic entities.[80]

Figure 13: Approved medicines and vaccines for selected diseases disproportionally affecting LMICs, 2000–2024

Abbreviations: BPM, Bacterial pneumonia and meningitis; HBV, hepatitis B virus; HCV, hepatitis C virus; HIV: Human immunodeficiency virus; TB: tuberculosis.

Source: Impact Global Health, 2024[80]

2.3 Groundbreaking innovation & the next generation of medicines

Thanks to groundbreaking innovations resulting from long and risky pharmaceutical R&D, **diseases previously considered deadly are now manageable or even curable**. Products once considered revolutionary like monoclonal antibodies (mAbs) are now commonly used in many (but not all) parts of the world and emerging treatment modalities, such as mRNA, may revolutionize patient management.[85] The pharmaceutical industry's push for innovation has resulted in recent breakthroughs in areas such as Alzheimer's disease, obesity management, cancer treatment, curative and disease-modifying gene therapy, gene editing technology, and vaccine development.[86] PhRMA reported that, as of September 2024, there were 1,181 preventive treatments in development addressing chronic conditions, such as cancers, heart disease, Alzheimer's disease, providing hope for people to live longer, healthier lives.[87]

Globally, over 55 million individuals are affected by dementia and, due to ageing populations, this number is expected to almost double every 20 years. **Alzheimer's disease** is the most common form of dementia.[88] While in 2019, clinical trials for Alzheimer's disease were associated with a 99% failure rate, years of persistent research have led to three novel treatments progressing through regulatory review and respectively reaching approval[89] in 2021,[90] in 2023,[91] and 2024.[92] By **targeting the amyloid plaques** that build up in the brains of patients, these revolutionary medicines go beyond addressing symptoms—slowing cognitive decline and improving quality of life.

In 2022, one in eight people globally were living with **obesity**, which poses serious risks to health, including contributing to cardiovascular disease and diabetes.[93] By 2030, almost 60% of the global population may be obese or overweight, underscoring the need for new approaches to manage this condition.[94] Obesity clinical trials in 2023 were up 68% compared with 2022.[52] **Glucagon-like peptide 1 (GLP-1) medicines** initially approved for treating type 2 diabetes have emerged as notable breakthroughs for obesity management.[95] While obesity rates have been climbing globally for decades, recent data shows that US adult obesity rate fell by roughly 2% between 2020 and 2023; while not certain, it is highly likely that the new generation of diabetes and weight loss drugs are behind this reversal.[96] Recent research suggests that weight loss injections could help reduce the risk of type 2 diabetes for people with obesity[97] and help to prevent heart attacks and other cardiac events.[98]

Biologic medicines already benefit more than 350 million patients globally, treating diseases like cancer, diabetes, and rare diseases.[99] Advanced therapy medicinal products (ATMPs) are next generation biotherapeutics based on genes, tissues, or cells, offering groundbreaking treatment opportunities. Gene therapy (transferring of genetic material to a patient to treat a disease) holds promise for various conditions including inherited disorders, some cancers, and rare genetic disorders. Cell therapy (restoring/altering certain cells or using cells to carry a therapy through the body) may reduce or eliminate the need for long-term treatments.[99] In 2023, six first-in-class[vii] cell and gene therapies launched (a 50% increase from the three launches in 2022 and 2021),[52] including the first gene therapy to treat Duchenne muscular dystrophy (DMD), a rare and serious genetic disorder that progressively worsens, causing muscle weakness and degeneration[100] and the first gene therapy to treat Hemophilia A, which in severe cases can cause life-threatening health issues due to increased risk of uncontrolled bleeding.[101] Over the past 10 years, industry-sponsored trials for cell and gene therapy have more than tripled.[52]

vii First in class is based on FDA classification.

Cancer immunotherapy, which is creating therapeutic cancer vaccines and treatments to stimulate the body's immune system to target and eliminate cancerous cells, has revolutionized oncology treatment. Enhanced understanding of how to regulate immune checkpoints, genetically modify immune cells, and boost immune responses against tumors has led to the development of various innovative cancer medicines.[102] By the end of July 2023, the US FDA had approved 11 immune checkpoint inhibitors (ICIs).[103] These groundbreaking treatments are being approved for an increasingly wide range of cancer types, and, by end of July 2023, there was at least one ICI approved for 20 cancer types and for any type of solid tumor.[103] Another form of immunotherapy, CAR T-cell therapy, uses T-cells to help the immune response kill cells infected by pathogens and target cancer cells. CAR-T cell therapy has proven to be an exceptionally effective treatment for blood cancers and available CAR T-cell therapies are customized for each individual patient.[104] As of August 2024, the US FDA had approved six CAR-T products.[105]

Better understanding of the role of genes, driven by the completion of the Human Genome Project in 2003 and the development of affordable DNA sequencing methods, has enabled the emergence of targeted therapies and precision medicine. **Precision medicine**, which has already unlocked novel avenues for preventing, diagnosing, and treating various diseases,[106] utilizes information about individuals' biological, environmental, and health behavioral characteristics to inform and tailor care.[106] For instance, oncologists use genetic tests to identify tumors to which treatments are likely to respond to. Furthermore, to accelerate R&D for precision medicines, pharmaceutical companies are building partnerships to leverage external genetic databases. An example is the 23andMe database, the world's largest resource of genetic and phenotypic information from consented participants, which is allowing some companies to conduct drug target discovery and other research.[107]

Ongoing **genomic research** has expanded the understanding of disease mechanisms and helped to identify potential therapeutic targets and prioritize the most promising ones. By 2018, 42% of US FDA approvals were for personalized medicines, linked to a diagnostic test or disease sub-group, a doubling from 2014.[108]

A particularly efficient gene-editing technology is the clustered regularly interspaced short palindromic repeats (CRISPR)/CRISPR-associated protein 9 (Cas9).[109] **CRISPR/Cas9**, which can correct mutations or disrupt disease-causing genes, may revolutionize treatment for many conditions.[110] At the end of 2023, the US FDA approved the first CRISPR/Cas9 gene-editing therapy for sickle cell disease.[111]

R&D is not a linear process. Often, during R&D, companies explore compounds and vaccine platforms targeting a specific disease but end up finding that these may be promising for other diseases. Similarly, for COVID-19 vaccines, researchers could leverage pre-existing insights around pathogens and technology platforms. Previous investments in mRNA research to treat cancer helped to prepare this technology for a practical application, making it ready to be tested for COVID-19 vaccines.[112] **The first COVID-19 vaccine was the fastest vaccine ever developed**, gaining approval only 326 days after the SARS-CoV-2 viral genome sequence was released in January 2020.[113] Today, the mRNA technology is being studied widely and it is hoped that it could revolutionize infectious diseases but also cancer and immunological disorders. Since the COVID-19 pandemic, RNA and DNA vaccines have increasingly been studied in these areas.

2.4 Some trends shaping pharmaceutical innovation

Advances in artificial intelligence (AI) could revolutionize clinical research, thanks to its application in medicine development, clinical trials, and disease diagnosis. Tools powering AI and **machine learning** (ML) may help to analyze extensive data sets, identify drug targets and promising compounds, and also help with early detection of adverse drug reactions and toxicity even before a drug is synthesized or undergoes preclinical and clinical trials.[114] AI/ML models may also help to increase diversity in clinical trials by identifying the right patients for the right studies at the right time.[115] Between 2015 and 2023, AI-native biotechs and their pharmaceutical partners introduced 75 molecules into clinical trials, with 67 of them still undergoing trials as of 2023, marking a remarkable growth trajectory in the past decade, with a compound annual growth rate (CAGR) exceeding 60% (Figure 14, Figure 15).[116] Most AI-discovered molecules are in Phase I, although some have advanced to Phase II and beyond.

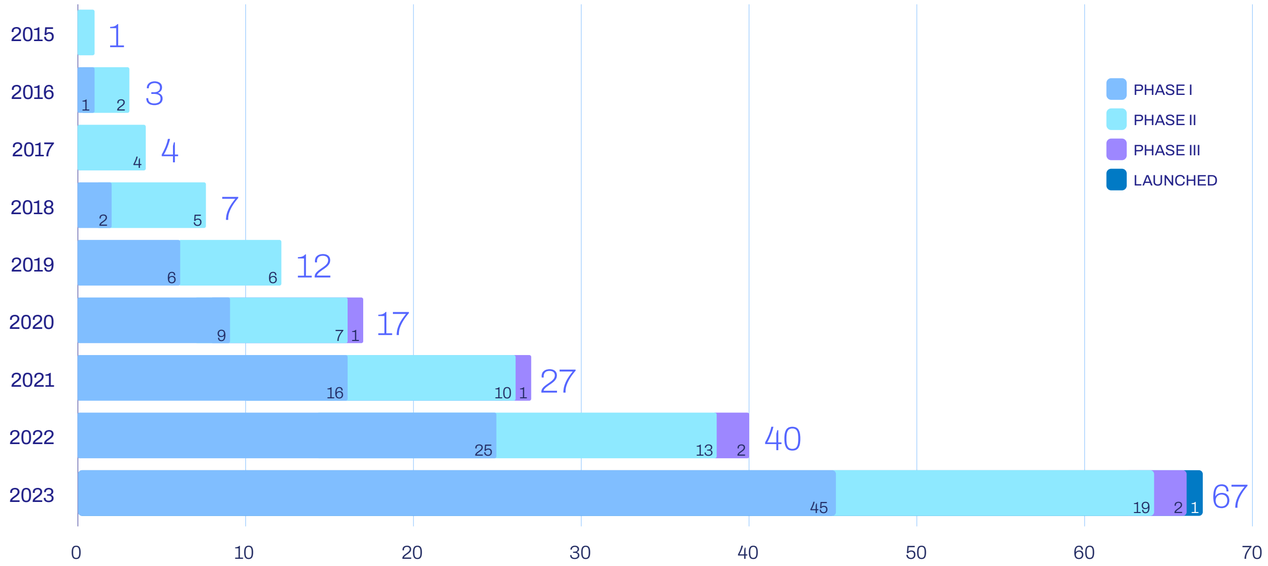


Figure 14: Number of AI-discovered molecules in clinical trials

Abbreviation: AI, artificial intelligence.

Source: Jayatunga et al, 2024[116]

Digitalization is impacting the drug development process, from early discovery to regulatory approval. Use of **digital health technologies (DHTs)**, such as wearable devices, drug-digital device combinations and electronic health records, offer new opportunities for data collection, patient monitoring, and remote participation.[115]

The use of **decentralized clinical trials** (DCTs) accelerated during the COVID-19 pandemic, marked by strict movement restrictions. Hybrid and/or fully virtual DCTs may use telemedicine, electronic consent collection, and wearable devices to collect data, allowing the collection of real-world data (RWD), potentially reducing site visits, and enhancing environmental sustainability and the patient experience. DCTs can also foster **diversity in clinical trials** by removing geographical barriers to patient participation.[117]

Innovative trial designs offer opportunities to increase efficiency in medical research. Novel trial designs, including umbrella, basket, master, and adaptive protocols, constitute a considerable part of the clinical trial pipeline, and have been included in roughly 18% of clinical studies between 2021 and 2023.[52] In 2023, innovative trial designs were used most commonly in oncology trials, accounting for 29% of these studies.[52]

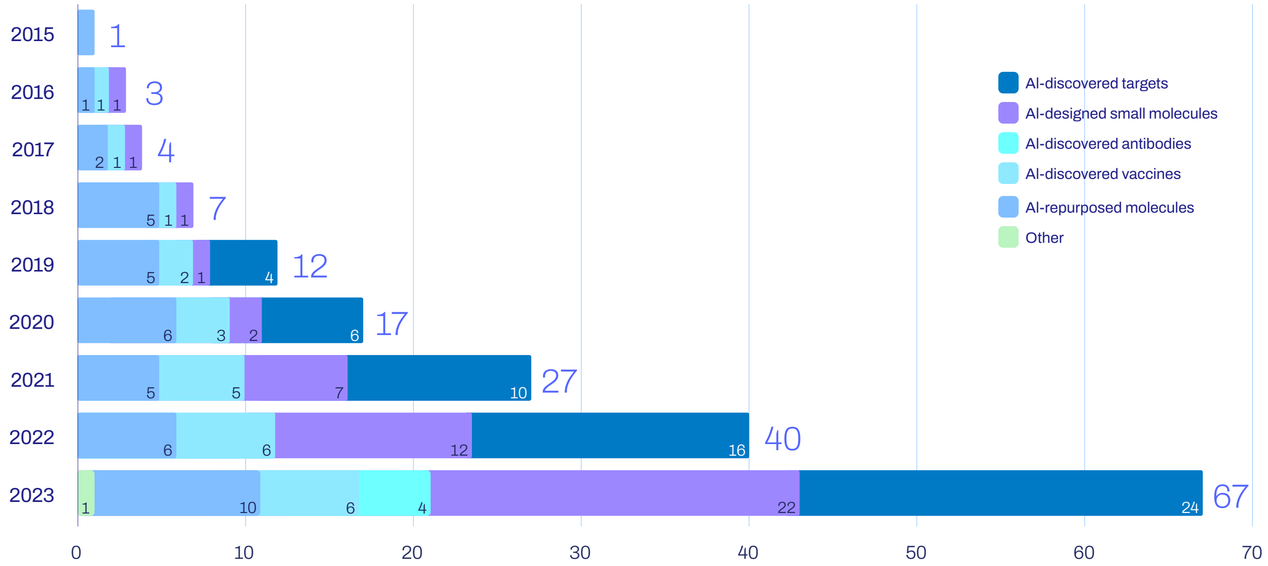


Figure 15: Number of AI-discovered molecules by mode-of-discovery in clinical trials

Abbreviation: AI, artificial intelligence.

Source: Jayatunga et al, 2024[116]

Innovative and technology-driven enablers are being embraced by both the pharmaceutical industry and National Regulatory Authorities.

Furthermore, **the collection of RWD and the application of realworld evidence (RWE)** continues to expand. Companies are not just using RWE to satisfy post-marketing requirements, but also to showcase product safety and efficacy in regulatory submissions. By the end of 2020, RWE was already part of the regulatory submission for 90% of new medicines approved in the US.[118]

Overall, innovative and technology-driven enablers are being embraced by both the pharmaceutical industry and NRAs (i.e., use of predictive biomarkers, innovative trial design, digital and decentralized trial approaches) contributing to productivity gains.[52] Looking ahead, further efficiencies are anticipated with the use and enhancement of innovative AI-powered approaches in R&D.[52]

3

Driving progress in global health

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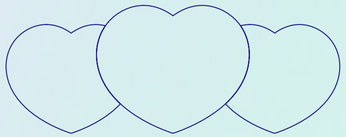
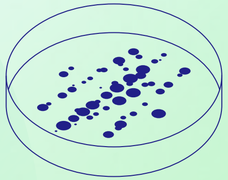
KEY FACTS AND FIGURES

Driving progress in global health



154m

Vaccines preventing over **30 life-threatening diseases** have been developed. Global immunization has **saved an estimated 154 million lives**, averaging six lives saved every minute of every year for the past 50 years.

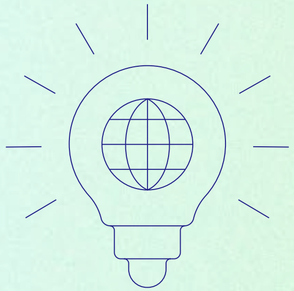


75%

Penicillin is estimated to have saved between **80-200 million lives** since its discovery. Without its discovery and implementation, **75% of people today would not be alive**, as their ancestors would have died due to infections.

40%

Vaccination against 14 diseases (including diphtheria, hepatitis B, measles, meningitis A, pertussis, polio, rotavirus, rubella, tetanus, tuberculosis, and yellow fever) directly contributed to a **40% reduction in infant deaths globally** over the past 50 years.

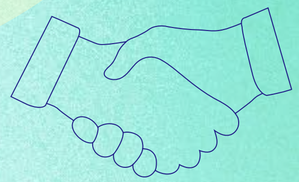


USD 12t

A study based on data from over 200 countries showed that investing in prevention and health innovation, over two decades, could save **60 million lives** and **add USD 12 trillion (or 8%) to global GDP** by 2040 (0.4% faster growth every year).

7x

In 2021, it was calculated that investment in non-communicable disease (NCD) prevention and control would yield an annual **7-fold** return in low- and middle-income countries (LMICs) within a decade. This could lead to an expected **USD 230 billion** economic gain by 2030.



260

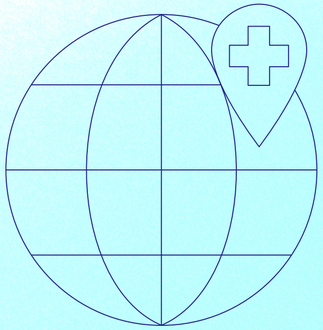
Companies, either individually or in partnership with other stakeholders, are making efforts to strengthen health systems and improve access to medicines. The pharmaceutical industry collaborates in more than **260 cross-sectoral, multi-stakeholder initiatives** with **over 1,100 partners** to support the achievement of the Sustainable Development Goals (SDGs).

3. Driving progress in global health

3. Driving progress in global health

Global health challenges, such as emerging and re-emerging infectious diseases, non-communicable diseases (NCDs) and climate change have detrimental effects on people worldwide, particularly those living in low- and middle-income countries (LMICs). Coordination from the global stakeholder community is fundamental to tackle these complex issues. Medicines and vaccines are key components of healthcare systems, and offer value from health, economic, and societal perspectives. Advances in pharmaceutical innovation have allowed people to live longer lives, revolutionized the management of several diseases, and enabled people to actively participate in society and contribute to economic growth. Despite this key role of medicines and vaccines for societies, access to medicines and quality healthcare is poor for many people around the world and especially in LMICs, primarily due to local factors. Recognizing this, pharmaceutical companies engage in various initiatives to strengthen health systems, improve access to medicines, and support the achievement of the Sustainable Development Goals (SDGs).

3.1 Tackling global health challenges



Urgent global health challenges include ageing populations, the growing burden of non-communicable diseases (NCDs), AMR, climate change, and the threat of pandemics. These challenges can be aggravated by factors such as rapid urbanization, conflicts, and displacement of people, which may affect key components of the patient journey and disrupt access to medicines. These global health challenges are complex issues that transcend national boundaries and governments and require coordinated efforts from the global community. Pharmaceutical companies are taking steps to address them, developing voluntary partnerships and multi-faceted solutions that recognize the interconnectedness of many of these trends and challenges.

3.1.1 Ageing population

Pharmaceutical innovations as well as technological, medical, and societal advances have allowed many people to live longer, unlocking new opportunities for individuals and societies. **But ageing populations pose challenges to societies and healthcare systems**. As people get older, they suffer an increased incidence of NCDs and infectious diseases with greater symptom severities (such as shingles and pneumococcal disease), comorbidities, and may need long-term and/or costly healthcare services.[119]

Worldwide, all regions are experiencing population ageing and this trend is expected to continue in the coming decades. In developed countries, the proportion of people aged 65 years and over is expected to rise from 20% to about 28% between 2023–2050.[120] While an ageing population is commonly perceived as a challenge for developed countries, populations in LMICs are also growing older. Between 2023–2050, the number of people aged 65 and over in the least developed countries is expected to nearly triple, whereas it will more than double in other developing countries (Figure 16).[120]

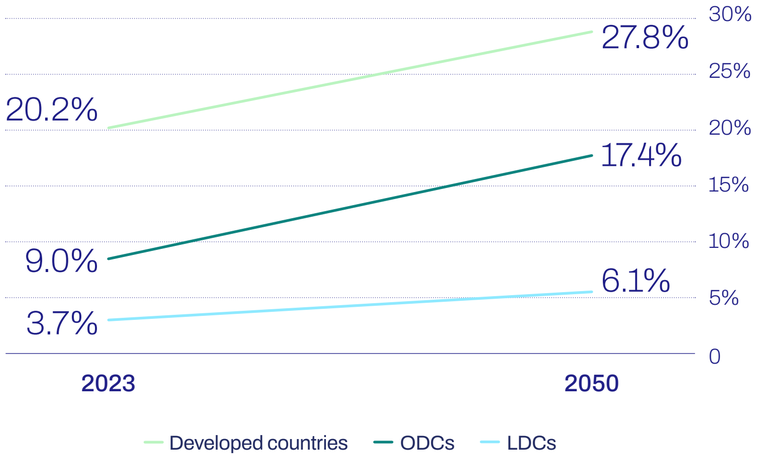


Figure 16: Proportion of persons aged 65 years and over by development group, 2023 & 2050

Abbreviations: ODCs, other developing countries; LDCs, least developed countries

Source: United Nations, 2023[120]

3.1.2
Non-communicable diseases (NCDs)

NCDs are a key global health threat, causing 41 million deaths annually, or **74% of all deaths globally**.[121] They include diseases like stroke, cancer, and diabetes and may result from a combination of genetic, physiological, environmental, and behavioral factors. Every year, 17 million people die prematurely from a NCD (before 70 years old), with 86% of these premature deaths occurring in LMICs.[121] Risk factors include unhealthy diets, physical inactivity, tobacco and alcohol use, and exposure to air pollution.[121] To address NCDs, the WHO proposed a list of highly cost-effective and feasible interventions, referred to as "best buys," including measures to reduce use of tobacco, harmful use of alcohol, unhealthy diet, physical inactivity, as well as use of specific medicines, vaccines, and screenings for NCDs.[122]

Cardiometabolic diseases, including cardiovascular disease (CVD), stroke, diabetes, and non-alcoholic fatty liver disease, contribute every year to over 30% of global deaths.[123]

Together, heart disease, stroke, diabetes, and kidney disease are responsible for more than 20 million deaths yearly.[124]

CVDs are the primary cause of death globally and are estimated to be responsible for taking 17.9 million lives each year.[125] CVDs include disorders that affect the heart and blood vessels, such as coronary heart disease, cerebrovascular disease, rheumatic heart disease, and various other conditions.[125] By 2030, the total global cost of CVD is expected to rise (from roughly USD 957 billion in 2015) to a USD 1,044 billion, with 55% of this cost attributed to direct healthcare costs, and 45% to indirect costs, primarily productivity losses.[124]

Adult **obesity** has more than doubled and adolescent obesity quadrupled since 1990.[93] In 2022, one in eight persons were living with **obesity** globally, with the prevalence of **diabetes** also rising in LMICs.[126] It is projected that, by 2035, half of the global population will be living with obesity.[123]

Cancer is the second leading cause of death globally, accounting for almost 10 million deaths in 2020.[127] Globally, the rates of cancer incidence are projected to increase by roughly 55% between 2020–2040.[128] In the 30 years between 2020 to 2050, the global economic cost of cancer is estimated to be about USD 25 trillion, which corresponds to an annual tax of 0.55% on global gross domestic product (GDP).[129]

Over 55 million people globally have **dementia**, with more than 60% of them in LMICs.[88] The global economic burden of **Alzheimer's disease** and related dementia is estimated to reach between USD 11.3 - 27.3 trillion by 2050, with LMICs expected to bear 65% of that economic burden.[130]

While pharmaceutical innovation has enabled significant progress in the treatment and management of NCDs, unmet medical needs remain. Ongoing efforts to advance R&D and expand prevention, screening, and access to medicines in LMICs will be essential to tackle NCDs.

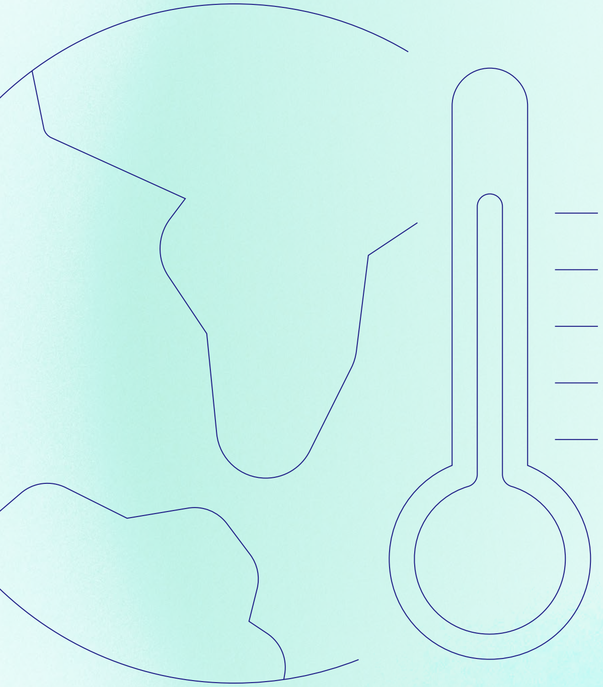
3.1.3
Antimicrobial resistance (AMR)

Antimicrobials are instrumental in treating infections and have inarguably been one of the greatest discoveries in medicine. In just over 100 years, antibiotics have extended human lifespan by roughly 23 years.[131] But AMR is a natural phenomenon, as bacteria, viruses, fungi, and parasites evolve and adapt to become less responsive to antibiotics, making infections harder to treat.[132] It is estimated that AMR could be directly responsible for the death of 1.9 million in 2050 — almost a 70% increase from the 1.1 million deaths in 2021.[133] AMR is also projected to contribute to the death of 8.2 million people in 2050 — almost a 75% increase from the 4.7 million associated deaths in 2021.[133] As explained in Chapter 2, due to the limited commercial viability of investing in antibiotic R&D and the resulting drain of AMR-relevant R&D expertise,[134] implementing R&D incentives will be crucial to reinvigorate the antibiotic pipeline and treat patients with infections resistant to current treatments. AMR clearly threatens progress toward the United Nations' 2030 SDGs[135] and **LMICs are particularly impacted,** due to their higher burden of communicable diseases and other poverty-related factors (such as scarce WASH infrastructure and access to antibiotics and diagnostics). Various stakeholders are engagingin initiatives to reduce AMR. Notably, in June 2023, an independent certification scheme was launched in partnership between AMR Industry Alliance (AMRIA) and BSI to support **responsible antibiotic manufacturing**,[136] following the initial AMRIA antibiotic manufacturing standard of 2022 also facilitated by BSI.[137]

Implementing R&D incentives will be crucial to reinvigorate the antibiotic pipeline.

Vaccines play an important role in preventing the spread of AMR, helping to prevent bacterial disease, which can reduce the need for antibiotics and slow the development of resistance. Furthermore, vaccines against certain viral diseases, like influenza, can reduce inappropriate antibiotics use and help to prevent secondary bacterial infections.[138]

A recent report by WHO found that the impact of 44 vaccines – including those in development – against 24 pathogens could, annually, avert more than half a million deaths associated with AMR, reduce antibiotic use by 22% or 2.5 billion doses, and reduce healthcare costs by up to USD 30 billion.[139] However, their value in addressing AMR tends to not be fully recognized and a 2022 study found that only in 33 WHO Member States (43%) AMR National Action Plans include concrete indicators (such as strategic objectives) to capture the role of vaccines against AMR.[140]



3.1.4
Climate change

The influence of climate change on global public health is becoming increasingly evident. Changes to weather patterns, such as temperature, rainfall, and humidity, can lead to the **spread of vector-borne diseases like malaria, dengue, Zika virus, and Lyme disease into new areas**. For instance, in 2023, the US issued a health alert after cases of locally-transmitted malaria were identified in Florida and Texas.[141] Furthermore, a mosquito species, vector of the chikungunya and dengue viruses, is establishing itself further north and west into Europe. Another species that can spread dengue, yellow fever, chikungunya, Zika and West Nile viruses is already established in Cyprus.[141] A 2023 study estimated that, in some regions, climate change could lead to a 20% increase in cases for viruses like dengue, Zika, and chikungunya over the following 30 years.[142] Climate disasters and drought can be responsible for use of unsafe drinking water, increasing the risk of waterborne diseases such as diarrhea and cholera. A 2022 analysis highlighted that 58% (218 out of 375) of the infectious diseases studied were aggravated by climate change.[143] Due to rising temperatures exacerbating the spread of some diseases, approximately 500 million more individuals globally could be at risk of contracting diseases like chikungunya and dengue, which could double to one billion cases by 2080.[144]

The direct health damage costs of climate change are estimated to reach USD 2–4 billion per year by 2030.[145] Between 2030–2050, climate change is projected to result in an additional 250,000 deaths annually due to malnutrition, malaria, diarrhea, and heat stress.[145] Warmer temperatures are linked to faster bacterial growth and higher infection rates and can push microbes to mutate and increase resistance to antibiotics. A recent study in China showed that, for every 1°C rise in temperature, there was a 14% increase in drug-resistant Klebsiella pneumoniae infections and a 6% rise in drug-resistant Pseudomonas aeruginosa infections.[146]

In addition to developing medicines and vaccines that can address the health effects linked to climate change, **many pharmaceutical companies are also striving to minimize the environmental footprint** of their operations and products. Efforts involve reducing carbon emissions across operations and value chains, investing in renewable electricity, and enhancing energy efficiency, decreasing water use, and recycling.[147]

3.1.5
Pandemics

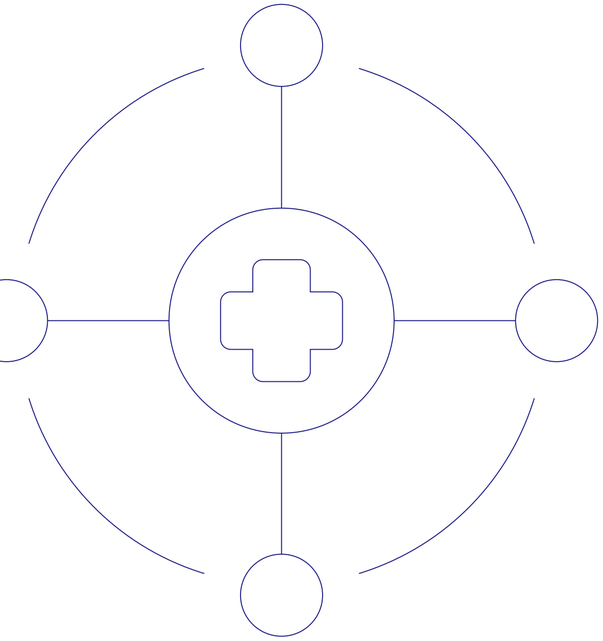
Pandemics will continue to pose a threat to global public health, as pathogens can quickly spread across countries. According to risk modelling estimates from Airfinity, there is a 27.5% chance of a pandemic similar to the COVID-19 pandemic occurring in the next ten years.[148] At the moment, 60% of known infectious diseases in humans and 75% of all emerging infectious diseases are zoonotic, meaning they transmit between animals and humans.[149] COVID-19 is a zoonotic illness. Similarly, Ebola, SARS, Zika, and bird flu (Avian influenza A) were all transmitted to humans through animals.[149] Human activities such as deforestation, increased international travel, urbanization, but also climate change and a fast-growing global population increase the risk of pandemics.[150] In particular, the COVID-19 pandemic demonstrated the importance of stakeholders' preparedness to help prevent and address pandemics.

In collaboration with the global community and broader life sciences sector, pharmaceutical companies responded to the COVID-19 pandemic with unprecedented speed and scale. These efforts resulted in the fastest vaccine development ever, with a record time of 326 days from genome sequencing to regulatory approval.[151] Companies' ability to build on pre-existing research on pathogens and technology platforms, and collaboration and global sharing of information on emerging pathogens, were critical to advance innovation. By the end of 2021, 32 vaccines had received emergency use authorization from NRAs and/or the WHO and approximately 11 billion doses were produced, underscoring the industry's ability to quickly scale-up manufacturing. It is estimated that this response prevented almost 20 million deaths globally.[152] For further details on partnerships for COVID-19 vaccines and medicines, please refer to **Section 1.1.2**.

Despite rapid pharmaceutical innovation and unprecedented levels of voluntary collaborations in responding to the pandemic, global **vaccine distribution faced several challenges** (such as trade barriers, vaccine nationalism, fragile supply chains, and health systems), which led to inequitable distribution. By February 2022, 90% vaccine coverage was achieved in many high-income countries (HICs), but only about 11% of people in LMICs had received at least one dose.[152]

Recognizing the challenges of vaccine distribution in the context of a pandemic, the Biotechnology Innovation Organization (BIO), Developing Countries Vaccine Manufacturers' Network (DCVMN), and the IFPMA, representing vaccines innovators and manufacturers, agreed to jointly endorse the Berlin Declaration framework, which outlines how the industry would reserve a portion of vaccine production for distribution to priority populations in lower-income countries during future global pandemics.[153, 154] The pharmaceutical industry proposed additional commitments for equitable access to essential medical countermeasures for future pandemics, as well as the creation of a multistakeholder Partnership for Equitable Access, to which companies can voluntarily associate by adopting a range of legally binding commitments.[155] Furthermore, an accord around pandemic prevention, preparedness, and response is currently being discussed among Member States of the WHO.[156] All these initiatives hold promise for an improved global response to future pandemics.

3.2 Medicines and vaccines as key components of different healthcare systems



Medicines and vaccines' key role in society

Investing in medicines and vaccines provides significant **health, economic, and societal value**. Pharmaceutical innovations improve people's quality of life, help to prevent and treat diseases, reduce the need for hospitalization, and contribute to the sustainability of healthcare systems (**read Section 3.3. for more details on advancements in treatment and management of various diseases**).

In the second part of the 20th century, **improvements in health have extended life and enhanced quality of life, contributing to expanding the labor force and productivity**, key factors behind strong economic growth in that period.[157] As countries became wealthier, they invested in healthier nutrition and safer environments, contributing to a cycle of improved health and higher incomes. Economists estimate that about one-third of economic growth in developed countries over the past century could be attributed to improvements in global health.[157]

Global immunization has already saved an estimated 154 million lives over the past 50 years.[158] By protecting people's health, immunization contributes to a healthy workforce, decreasing sick days, boosting productivity, and supporting economic growth. For instance, preventable diseases cause G20 economies to lose more than USD 1 trillion annually in productivity among people aged 50 to 64.[159]

A 2024 Office of Health Economics (OHE) report on the benefit-cost analysis of four adult **immunization programs** in 10 countries showed how these programs **can produce returns of up to 19 times their initial investment** to society when benefits beyond the healthcare system are quantified.[160] This return is equivalent to billions of dollars in net monetary benefits to society (or up to USD 4,637 for one individual's full vaccination course)[viii].[160]

viii Study details: The four immunization programs were against seasonal influenza (influenza), pneumococcal disease (PD), herpes zoster (HZ), and respiratory syncytial virus (RSV). The ten countries were Australia, Brazil, France, Germany, Italy, Japan, Poland, South Africa, Thailand, and the United States of America.

In the long term, a McKinsey study analyzing over 200 countries showed that investing in prevention and health innovation, over two decades (2020-2040), could save 60 million lives and add USD 12 trillion (or 8%) to global GDP by 2040 (0.4% faster growth every year).[157] These benefits arise through the labor market by expanding future employment via less early deaths, less health conditions, higher labor-force participation of healthier individuals, and through productivity gains attainable by physically and cognitively healthier workers.[157]

In 2017, the World Health Assembly endorsed a package of 16 affordable, cost-effective and evidence-based NCD interventions, the so-called NCD Best Buys, which focus on addressing the major NCD risk factors, such as tobacco use and management of priority disease areas, such as cardiovascular disease, diabetes and cervical cancer (including vaccination against human papillomavirus of girls).[161] According to a 2021 WHO study examining the costs and benefits of using the Best Buys for low-income countries (LICs) and LMICs, an investment of **one dollar in NCD prevention and control would yield a return of seven dollars, worth more than USD 230 billion by 2030**.[161]

Between 2007 and 2017, just a subset of medicines (including HIV and breast cancer treatments) in Europe added an estimated two million healthy years to patients, generating EUR 27 billion in productivity gains and around EUR 13 billion in healthcare savings from avoided complications.[162]

Universal health coverage (UHC)

UHC is a key target of the health-related SDGs and a key component of well-functioning healthcare systems. UHC covers the full continuum of essential health services, from health **promotion to prevention, treatment, rehabilitation, and palliative care** across the life course.[163] Despite this, UHC is not guaranteed in many countries. As of 2023, only 11% of countries worldwide adopted a concrete strategy to achieve UHC and only 17 out of 135 LMICs (13%) were expected to meet or exceed the projected necessary government spending to meet UHC goals by 2026.[164]

Reorienting health systems to **prioritize a primary health care (PHC)** approach is important for making progress toward UHC. According to the WHO, a PHC approach could deliver 90% of essential UHC interventions (including several key tests, vaccines, and medicines), potentially saving 60 million lives and raising the average global life expectancy by 3.7 years by 2030.[163]

Investing in prevention and health innovation, over two decades, could save 60 million lives and add 8% to global GDP by 2040.

Variations in health spending and its composition

The **composition of health spending** varies across countries of different income groups.[165] Generally, in wealthier countries, the share of health spending financed by government spending and social health insurance contributions is higher compared with poorer countries, where the share of health spending financed by out-of-pocket (OOP) spending is higher. **High OOP spending may lead to catastrophic health expenditure for vulnerable people.**

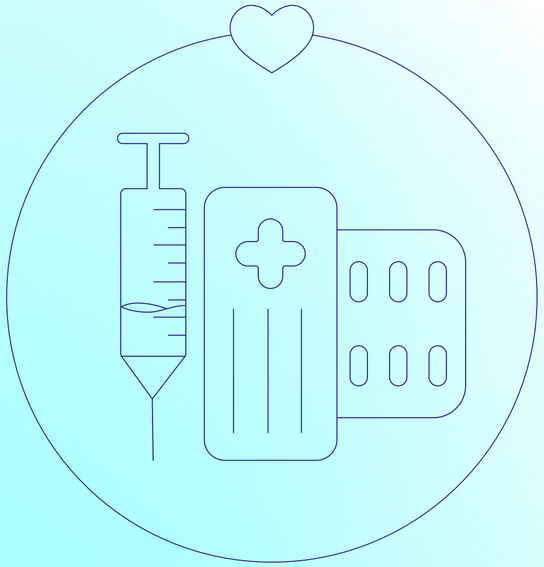
Health spending as a share of total government spending can indicate how much priority is given to health in public spending. In 2019, HICs spent a considerably larger share of GDP on health (14%) compared with LICs (5.4%).[165] In April 2001, via the Abuja Declaration, African Union governments set a target of allocating at least 15% of their national budgets to healthcare. Despite this, 2021 analysis revealed that only two out of the AU's 55 member countries — Cabo Verde and South Africa — had achieved this target.[166] **In 2021, African governments allocated on average only 7.4% of their national budgets to healthcare** — less than half of what they had pledged 20 years earlier, resulting in about 95% of the African population residing in countries that failed to meet this spending target during that year.[166] In Sub-Saharan Africa, recent estimates suggest that, while GDP was projected to increase through 2050, the percent of government spending dedicated to health is expected to stay low (7.2% compared to average of 12.4% in other regions).[167] Today, the world is considered far behind schedule to make substantial progress toward UHC coverage by 2030.

Barriers to equitable access to medicines

Despite the fundamental role of medicines and vaccines in improving health and societal outcomes, access to these products is far from equitable around the world. A country's level of economic development, political and economic choices, and healthcare system priorities will deeply influence financing, coverage, quality of care provided, and ultimately people's access to quality, affordable medicines and vaccines at the point of care.

Barriers to achieving equitable patient access to quality and affordable medicines in LMICs are complex and multi-faceted and go beyond simple pricing and affordability issues. They include **regulatory processes, procurement systems, funding and financing, distribution and supply chain, and health service delivery including diagnosis, capacity, and data**. These barriers mean that even low-priced, or free of charge, medicines are failing to reach patients at the point of care. For these reasons, overcoming challenges to UHC and access to medicines in LMICs require holistic solutions based on a deep understanding of country-level access pathways and the barriers/bottlenecks that are causing problems. Based on this understanding and the roles and responsibilities for different stakeholders to overcome the barriers, potential opportunities for collaborative efforts to unlock patient access at a local level can be taken forward.

3.3 Progress in the management of various diseases



Prescription medicines and vaccines have led to significant advancements in health, allowing people to live longer and healthier lives. For example, Penicillin, used for treating conditions such as pneumonia, ear, skin, and throat infections, has saved between 80-200 million lives since its discovery. **Without Penicillin's discovery and implementation, 75% of people today would not be alive as their ancestors would have died due to infections.**[168]

A study published in 2019 explored the role of pharmaceutical innovation (introduction and use of new drugs) in reducing the number of years of life lost before three ages (85, 70 and 55) in 27 countries (including HICs and LMICs). The study estimated that, if no new drugs had been launched after 1981, the number of years of life lost before 85 years old, would have been more than twice as high as it was in 2013.[169]

In the last 25 years, **medicines have revolutionized the treatment of numerous debilitating diseases and conditions** such as heart disease, HIV/AIDS, cancer, and hepatitis C, resulting in reduced deaths, improved health outcomes, and enhanced quality of life.

3.3.1 Vaccines

Vaccines are among the most impactful innovations in medicine. Nothing except for clean water has had a larger positive impact on global health.[170] Immunization is one of the most cost-effective public health interventions, and an indispensable component of primary healthcare.

Vaccines preventing over 30 life-threatening diseases have been developed.[158] Global immunization has saved an estimated 154 million lives, averaging six lives saved every minute over the past 50 years.[158] Vaccination against 14 diseases (including diphtheria, hepatitis B, measles, meningitis A, pertussis, polio, rotavirus, rubella, tetanus, tuberculosis, and yellow fever) directly contributed to a **40% reduction in infant deaths globally** over the past 50 years.[158] Just in the African region, vaccines are estimated to have saved roughly **51.2 million lives over the past 50 years**.[171]

Vaccinations prevented over **14 million deaths from COVID-19** in 185 countries and territories between December 2020 and December 2021. This estimate rose to over 19 million deaths averted when excess deaths are used as an estimate of the true extent of the pandemic, highlighting a global reduction of 63% in total deaths in the first year of COVID-19 vaccination.[172]

Vaccines have successfully worked to eradicate, eliminate, or control many diseases. Smallpox has already been eradicated, and polio could soon be eradicated.[173] Polio has been reduced by more than 99% and vaccination against it has enabled 20 million people to walk today who would otherwise have been paralyzed.[174] According to the WHO, diseases such as measles, mumps, and rubella could be eliminated from some parts of the world.[173] During 2000–2022, measles vaccination alone prevented approximately 57 million deaths worldwide.[175] **Various vaccines lead to a 100%, or near 100%, reduction in the risk of death** for some diseases that caused significant morbidity and mortality before vaccines' introduction (Figure 17).[176] Furthermore, some vaccines can lower the risk of developing cancer and other chronic illnesses, such as the human papillomavirus (HPV) vaccine, which is at least 94.7% effective in preventing HPV infections.[12] Thanks to vaccination, cervical cancer could be eliminated in our lifetime in some countries for the first time ever.[177]

Vaccines have played a key role in protecting **child and adolescent health**, fundamental to ensure healthy populations. Recent successes include the first pneumococcal conjugate vaccine licensed in the year 2000 addressing pneumonia, one of the main killers of children under five years old. This breakthrough enhanced previous versions that did not generate consistent immunity in children.[28] In 2006, the first vaccine for rotavirus was approved, the most common cause of diarrheal disease in infants and young children. Overall, between **two and three million lives of children are saved** every year thanks to immunization. Despite this, one every five children still misses out on routine life-saving immunization,[28] underscoring the need to continue to expand immunization globally. In addition to being crucial for children and adolescents, immunization is important to **protect adults' health**, and can help to manage the global challenge of an ageing population (**read Section 3.2. for more details on the importance of adult vaccination**).

As demonstrated by their strong vaccine pipeline, the pharmaceutical industry is committed to developing new and improved vaccines to help prevent disease and save more lives. Recently developed vaccines against diseases like malaria, dengue, RSV, and cervical cancer hold promise for improved health impacts in the future.[178]

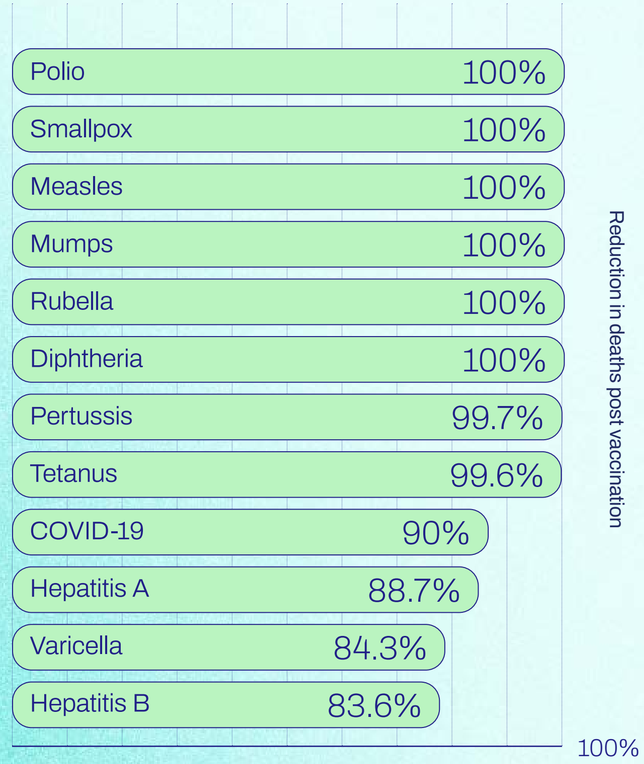


Figure 17: Diseases with vaccination and the percent reduction in deaths post vaccination

Source: Thomas and Wessel, 2023[176]

3.3.2 NCDs

Recent pharmaceutical innovations have significantly boosted survival rates for individuals with certain types of cancer, heart disease, and stroke across many countries.[157]

In the US, medicines are estimated to be responsible for more than a third of the improvement in life expectancy from 1990 to 2015.[179] In several disease areas, improvements in treatment thanks to biopharmaceutical innovation accounted for most of mortality changes (76% of improvements in mortality for patients with HIV; 60% for patients with breast cancer; 52% for patients with heart disease).[179]

Huge progress has been made on tackling cancer in the past 50 years, with more people surviving cancer today than ever before.[180] New medicines have contributed to declines in mortality rates and enhanced survival times for various cancer types.[181] A study looking across the 15 most common tumor types indicated that new cancer medicines approved between 2000 and 2016 in the US were associated with the prevention of almost 1.3 million cancer-related deaths.[182] Today, we know that cancer has over 200 different subtypes.[183] This awareness, combined with a deeper understanding of how cancer originates and progresses, has revolutionized care beyond prevention. Some breakthrough therapies have revolutionized patient outcomes, such as cancer immunotherapy that can work on different cancer types and offer the possibility for long-term remission.[184] **As outlined in chapter 2**, continuous innovations in immuno-oncology, cell and gene therapy, RNA therapy, and precision oncology provide promising ways to tackle cancer.[183]

Similarly, the pharmaceutical industry has gained a deeper understanding of how genetic, environmental, and lifestyle factors interact to influence **cardiometabolic conditions**, enabling the industry to develop new medicines. Cardiovascular medicines today treat various conditions such as arterial hypertension, arrhythmias, heart failure, and coronary artery disease.[185] **Statin medications** that lower cholesterol levels can substantially reduce the risk of heart attacks[186] and remain the most widely prescribed class of medications today.[2] They have extended the lives of millions of people at risk of heart attack and stroke, with minimal management: one pill a day.[2] In the future, precision medicine holds promise for a tailored and efficient approach to managing CVD prevention and treatment.[187]

3.3.3
Diseases disproportionately affecting LMICs and neglected tropical diseases

For several diseases that disproportionately affect people in LMICs (such as HIV, malaria, and TB), there is a need for new or improved products. In the last 20 years, deaths from these diseases have dropped by over 30%.[188]

HIV remains a key global health challenge, causing 630,000 deaths in 2022. Although there is no cure for HIV, progress in prevention, diagnosis, treatment, and care has transformed HIV into a manageable chronic condition.[189] Despite these advances, there are still regional disparities in their application, often leading to under-diagnosis and under-treatment in LMICs.

Malaria was responsible for 608,000 deaths in 2022, and the African region was home to 95% (580,000) of malaria deaths, with children under the age of five accounting for roughly 80% of all malaria deaths in the region. Today, there are vaccines and chemoprevention medicines available to reduce the risk of contracting malaria, and early treatment for mild malaria can prevent the infection from progressing to a severe state.[88]

TB, despite being a preventable and curable disease, leads to the death of 1.5 million people annually, making it the world's most infectious killer disease.[190] Drug-resistant TB accounts for one in three deaths caused by antimicrobial infections, more than any other drug-resistant infection.[191]

Despite the considerable burden that these diseases pose to the most vulnerable populations, some **'game changer' innovations in prevention, treatment, and diagnosis have already emerged**. Examples include ART for HIV/AIDS, early infant diagnosis, and viral load testing that diagnoses and confirms ART failure;[192] new medicines for the management of drug resistant TB[193] and nucleic acid amplification tests for diagnosing TB and drug-resistant TB;[194] and the approvals of the two malaria vaccines after decades of research.[195]

Neglected tropical diseases (NTDs) affect more than 1.5 billion people[196] and include various conditions prevalent in tropical areas, linked with catastrophic health, social, and economic impacts. Several multi-stakeholder initiatives have emerged to address funding and scientific challenges related to NTDs. In 2012, via the London Declaration on NTDs, pharmaceutical companies and other stakeholders committed to control, eliminate, or eradicate NTDs by 2020.[197] The Kigali Declaration in 2022 saw governments, pharmaceutical companies, donors, and non-governmental organizations (NGOs) renew their commitments to eradicate, eliminate, or control NTDs by 2030.[198] Commitments by pharmaceutical companies and other stakeholders included medicines donations, research funding, enhancing local manufacturing capacity, and co-financing initiatives to unlock private sector funding.[199] In 2021, 877 million people received treatment for NTDs, and, between 2012 and 2023, the pharmaceutical industry donated 17 billion treatments for NTDs.[200]

3.3.4
Hepatitis C virus

Hepatitis C is a blood-borne viral disease that develops gradually and, if not treated, can lead to liver inflammation and lifelong illness, including liver cirrhosis and cancer.[201] Approximately 71 million people live with chronic hepatitis C, resulting in nearly 400,000 deaths annually.[202]

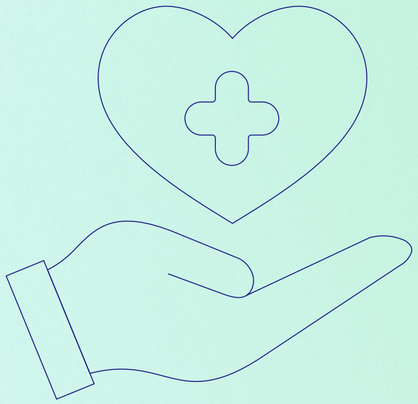
The journey for finding a cure for the hepatitis C virus (HCV) is a good example of how a robust innovation ecosystem can lead, step-by-step, from initial discovery to a cure in only 25 years. The HCV was first identified in 1989. While 77 investigational medicines failed during clinical research between 1998 and 2014, this research laid the groundwork for 12 approved medicines. A revolutionary new class of medicines, direct-acting antivirals (DAAs), was introduced in 2011 and today 98% of people can be cured through an 8-12 week course of medicines.[203] HCV was the fastest viral disease to ever be identified and cured and became the first chronic viral illness that can be completely cured.[204]

HCV was the fastest viral disease to ever be identified and cured and became the first chronic viral illness that can be completely cured.

Various countries are strengthening national preventive and treatment programs, which is yielding promising outcomes. For instance, Egypt managed to progress from having one of the world's highest rates of hepatitis C to one of the lowest by reducing the prevalence of hepatitis C from 10% to 0.38% in just over 10 years.[205]

Overall, access to HCV treatment is improving worldwide, but remains limited. In 2022, out of the 50 million people living with HCV, only about 36% were aware of their diagnosis. Among those diagnosed with chronic HCV infection, approximately 20% had received treatment with DAAs by the end of 2022.[201] Addressing the challenges related to access to treatment and diagnosis will be key to reduce new hepatitis infections and deaths.

3.4 Initiatives to facilitate access to medicines and vaccines



In addition to developing medicines and vaccines, pharmaceutical companies implement strategies and engage in **programs and partnerships to increase access to pharmaceutical products**, improve people's health, and support the achievement of the SDGs.

Companies often implement various access plans for their products in development to **facilitate accessibility and affordability in LMICs**. Out of 20 companies assessed by the 2022 Access to Medicine Foundation Index, six companies had access plans in place for 100% of late-stage R&D projects, the first time any individual company hit that milestone.[206] According to a 2024 report from the Access to Medicines Foundation, most companies included in the analysis (19 out of 20) established an approach to measure and track the patients they reach with their essential medicines in LMICs. Despite this, only 12 out of 42 approaches reported were considered comprehensive, signaling further scope for enhancement.[207]

Cross-sector collaborations

Companies form collaborations to strengthen healthcare systems and facilities, with the aim of increasing access to pharmaceutical products via tailored pricing, advancing sustainable financing, providing equipment and resources, enhancing regulatory and supply chain regimes, supporting training and education for healthcare professionals, and raising disease awareness.[208]

The Global Health Progress interactive hub highlights **more than 260 examples of cross-sector active collaborations** (as of September 2024) in which the innovative pharmaceutical industry is working on, **with over 1,100 cross sector partners** to support the achievement of the SDGs (Figure 18).[209] These partners may involve governments, academia and research institutes, PDPs, multilateral organizations, global and local NGOs, private foundations, and private companies (such as other innovative pharmaceutical companies, generic manufacturers, biotech and diagnostic companies, and health insurers). Collaborations focus on over 80 diseases and are customized to meet the health needs of local communities.[209]

Access Accelerated is an example of a partnership, created in 2017 among pharmaceutical companies, with the World Bank and key global health organizations as strategic partners, that aims to improve the prevention and treatment of NCDs in LMICs.[211] It supports countries and ministries to advance access to quality NCD care, including efforts to strengthen NCD financing. By 2023, this collaboration had catalyzed USD 3.7 billion in NCD investment, supporting over 35 LMICs.[212]

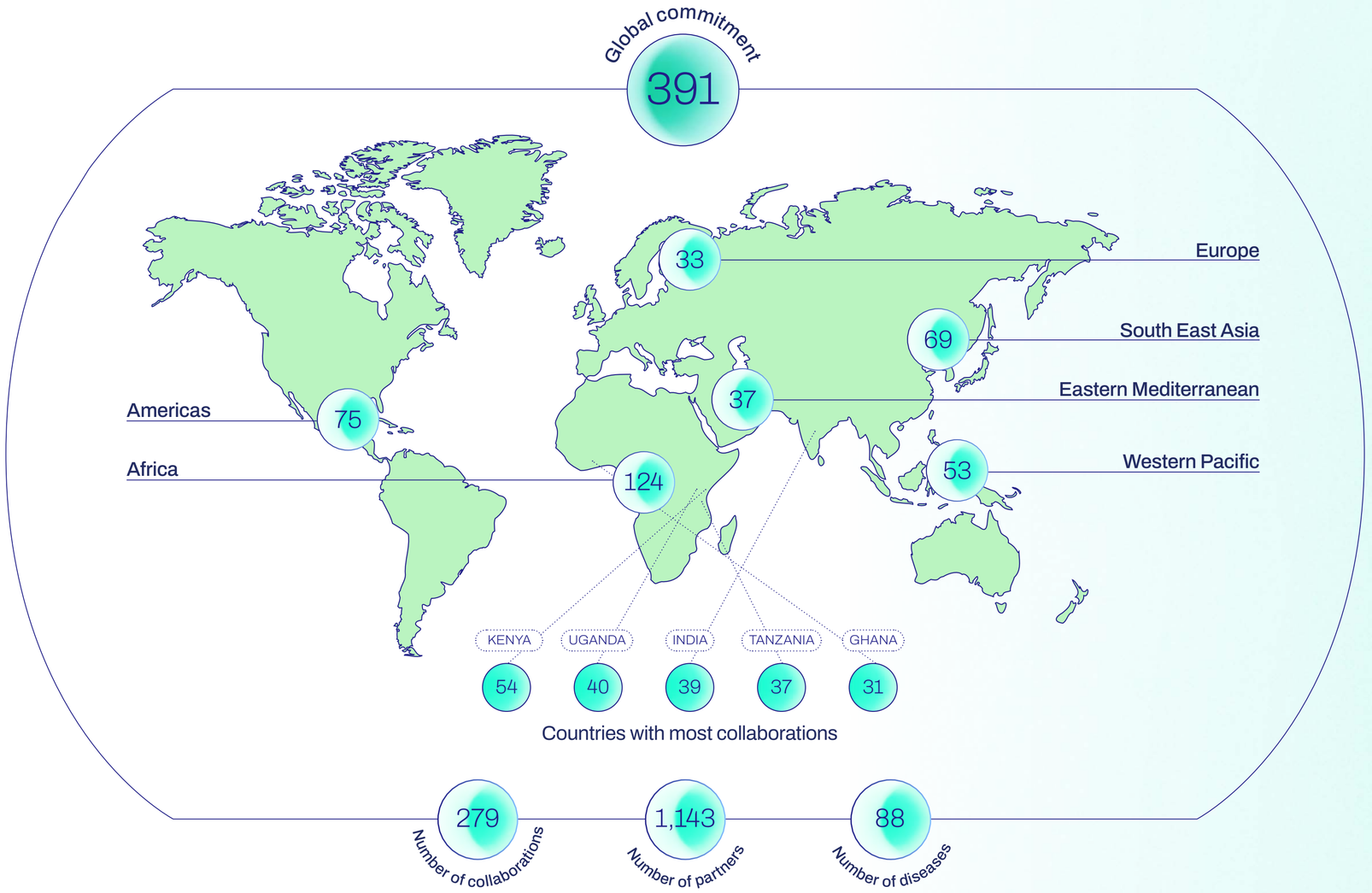


Figure 18: Cross-sector active collaborations between innovative pharmaceutical companies and their partners, September 2024

Source: IFPMA Global Health Progress, 2024[210]

Domestic resource mobilization is key to improving healthcare at a country level. This could be achieved by **supplementing and catalyzing domestic resources with innovative financing mechanisms**, such as value-based pricing (VBP), public-private insurance schemes, debt swaps, social impact bonds (SIBs), and advanced market commitments.[213]

Pricing

When setting a medicine's price, companies consider the value they bring to the country as well as the country's economic conditions. This approach ensures that medicines are accessible while also securing necessary funds for ongoing R&D to foster future innovations. Companies use **various pricing approaches to facilitate patient access** to medicines and vaccines, and tiered pricing (or differential pricing) is used to align prices with a country's relative wealth. Value-based pricing to help to strike a balance between facilitating access for as many people as possible, while incentivizing investment in future innovation. Outcome-based agreements to help to improve access by linking the price of a medicine to the outcomes it delivers.

When setting a medicine's price, companies consider the value they bring to the country as well as the country's economic conditions.

Voluntary partnerships

Companies engage in various voluntary partnerships, such as technology transfers and voluntary licensing, which contribute to improving access to medicines.

Via **technology transfers**, companies exchange knowledge, know-how, and show-how to develop medicines and vaccines based on expertise, experience, and trust.[214] To ensure the receiving company is able to properly absorb a technology and manufacture a product, several elements are important (i.e., skills and expertise to understand and adapt to new processes and technologies, sufficient manufacturing experience, ability to meet regulatory requirements, capacity to scale-up production).[215] Enabling factors for technology transfers in a certain country may include robust regulatory systems, political stability, and skilled workforce.[215]

The COVID-19 pandemic underscored the critical role of partnerships in expanding manufacturing capabilities without compromising the safety and quality of pharmaceutical products. These voluntary and diverse collaborations required close cooperation among partners.[216] The IP framework enabled an unprecedented level of collaboration during the pandemic and provided the basis for voluntary partnerships for scaling up the production of COVID-19 vaccines and therapeutics.[216, 217] Most of these partnerships involved technology transfers,[217, 218] which were key to enable the industry to swiftly expand global manufacturing capacity.

With voluntary licensing, a company grants rights to another party (often a local company) to manufacture or sell its patented product (as if it were a generic). Companies may decide to collaborate with a party based on various factors, such as the licensee's expertise and ability to maintain the product's quality standards.[215] For these reasons, voluntary licensing may not always be suitable, and, at times, companies might judge it more appropriate to facilitate access through other approaches (including non-assertion of IPRs, tiered pricing, procurement negotiations, marketing and distribution arrangements, contract manufacturing, donations).

Licenses can be arranged between companies bilaterally or via the **Medicines Patent Pool (MPP)**, a United Nations-backed organization that aims to increase access to life-saving medicines for LMICs (such as for HIV, HCV, and TB)[219] and that works with generic partners to speed the development and distribution of new treatments. So far, over 148 countries have benefited from access to MPP-licensed products, 22 patent holders have signed agreements with MPP, 57 generic manufacturers and product developers have sublicences from MPP, and more than 43 billion doses were supplied between 2012–2023.[220] In 2022, the MPP joined the Access to Oncology Medicines (ATOM) Coalition, a partnership to increase access to cancer medicines in LMICs and to help countries to develop capacity for their proper use.[221]

The Access to COVID-19 Tools Accelerator (ACT-A) was a global partnership established to accelerate the development, manufacturing, and distribution of COVID-19 medicines, vaccines, and diagnostics.[222] The ACT-A was launched in April 2020[223] to accelerate quick and affordable access to COVID-19 tests and treatments, with IFPMA a founding member. The COVAX facility was set up to facilitate equitable procurement and distribution of vaccines globally,[88] and delivered roughly 2 billion COVID-19 vaccines and injection devices to 146 economies.[224]

Despite the multiple strategies and initiatives, **continuous efforts are needed from governments and multiple stakeholders** to increase access to medicines and vaccines in LMICs and support the achievement of SDGs. Public-private partnerships in an ecosystem that fosters trust, sharing of best practices, and early engagement can help in this endeavor.

4

Contributing to the global economy and employment

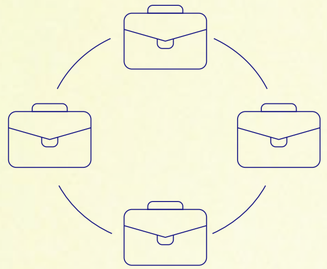
#AlwaysInnovating

KEY FACTS AND FIGURES

Contributing to the global economy and employment

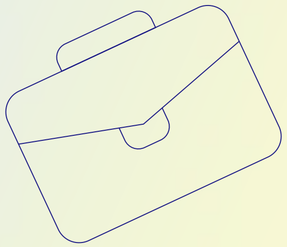
7.8m

Of the **7.8 million** people directly employed by the pharmaceutical industry in 2022, over 1 million were involved in R&D activities, demanding specialized technical skills and education.



8.54

For every job directly created by the industry's activities, another (indirect and induced) **8.54 jobs were supported along the global supply chain** in 2022.

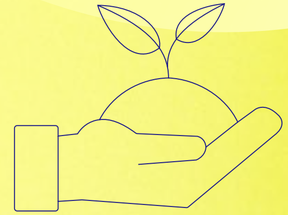


74.9m

The pharmaceutical industry supported the employment of **74.9 million people globally** in 2022 (including direct, indirect, and induced effects).

USD 2,295b

In addition to driving R&D, bringing new products to market, and improving people's well-being, the pharmaceutical industry brings added value to the global economy. Combined direct, indirect, and induced effects of the global pharmaceutical industry's total contribution to the world's gross domestic product (GDP) were **USD 2,295 billion** in 2022.



USD 2.04

In 2022, for every dollar of gross domestic product (GDP) directly generated by the pharmaceutical industry, a further **USD 2.04 in value** was created along the global supply chain.

4. Contributing to the global economy and employment

4. Contributing to the global economy and employment

The pharmaceutical industry is the most R&D intensive among similar R&D-intensive industries. In addition to its contribution to innovation and improvements in individuals' quality of life, the activities of the pharmaceutical industry positively impact the global economy, having direct, indirect, and induced effects on the global gross domestic product (GDP). The industry also contributes to sustaining the global workforce and employs many people in R&D, which require specialized training, technical skills, and education.

4.1 Contribution to GDP

Beyond its contributions to research, innovation, and improved health outcomes, the pharmaceutical industry plays an important role in the global economy. An economic impact study published by the WifOR Institute[225] in 2024 estimated the global pharmaceutical industry's value in terms of its contribution to GDP and the jobs it supports. Recognizing R&D as a driver of economic performance and national prosperity, the study considered R&D activities as value components to the total GDP contribution.

According to the 2024 WifOR Institute study, the **pharmaceutical industry contributed a total of USD 2,295 billion to the global GDP in 2022, considering direct**[ix]**, indirect**[x] **and induced**[xi] **effects** (Figure 19). The economic activity of the pharmaceutical industry generated USD 978 billion in indirect effects and an additional USD 562 billion attributed to induced effects in other industries.[225]

The industry's direct contribution amounted to USD 755 billion, representing 0.7% of the global GDP or roughly equivalent to Switzerland's GDP in 2022. The direct GDP contribution has increased by more than 20% in the past decade, from USD 623 billion in 2012 to USD 755 billion in 2022 (Figure 20).[225]

The spillover effects of the pharmaceutical industry activity have considerable positive impact on the global economy. These effects encompass both indirect economic effects and economic effects induced by private consumption. It was estimated that, **for every USD 1 of GDP directly generated by the industry, an additional USD 2.04 in value is created along the global supply chain**.[225]

The 2024 WifOR Institute study also estimated that **R&D activities within the global pharmaceutical industry alone contributed USD 227 billion to the GDP in 2022 directly**, constituting approximately 30% of the industry's total direct GDP contribution. This figure reflects a 49% increase from 2014 (USD 152 billion).[225]

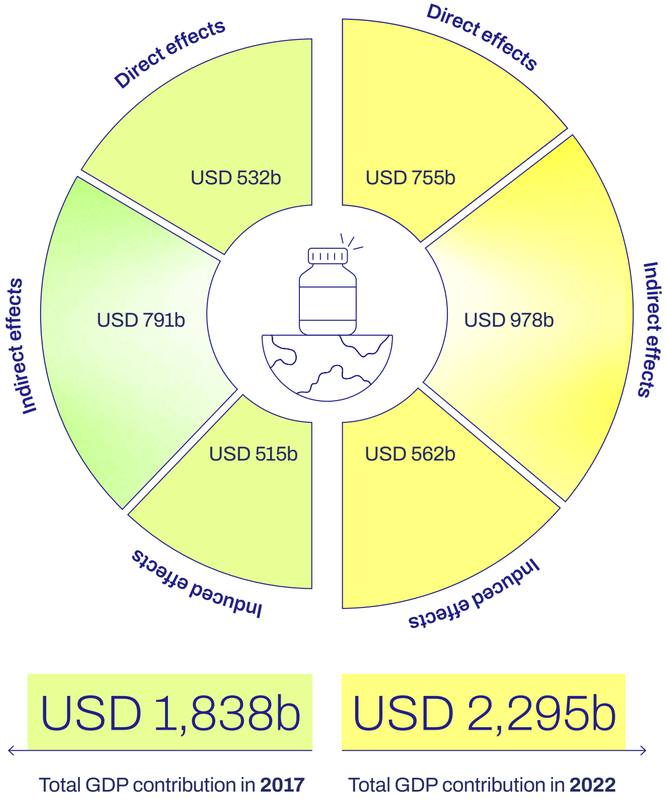


Figure 19: Direct and spillover GDP contribution effects of the global pharmaceutical industry, 2017 and 2022

Abbreviation: GDP, gross domestic product.

Source: WifOR Institute, 2024[225]

ix Direct (economic) effects: Direct contribution of a company or sector to the economy. What did the company generate in terms of economic value? These direct effects are reflected in the economic output of a company, or its value added or the number of employed persons (details extracted from the WifOR study).

x Indirect (economic) effects: Production activities of a company or sector require purchased materials and services. Such purchased materials and services in turn result in increased production among suppliers who also require purchased materials and services for their own production process. The cascading effects that develop as a result (e.g. employment, gross value added) are referred to as the indirect economic effects of the enterprise (details extracted from the WifOR study).

xi Induced (economic) effects: Refer to those economic effects that result from renewed spending of directly and indirectly generated incomes (details extracted from the WifOR study).

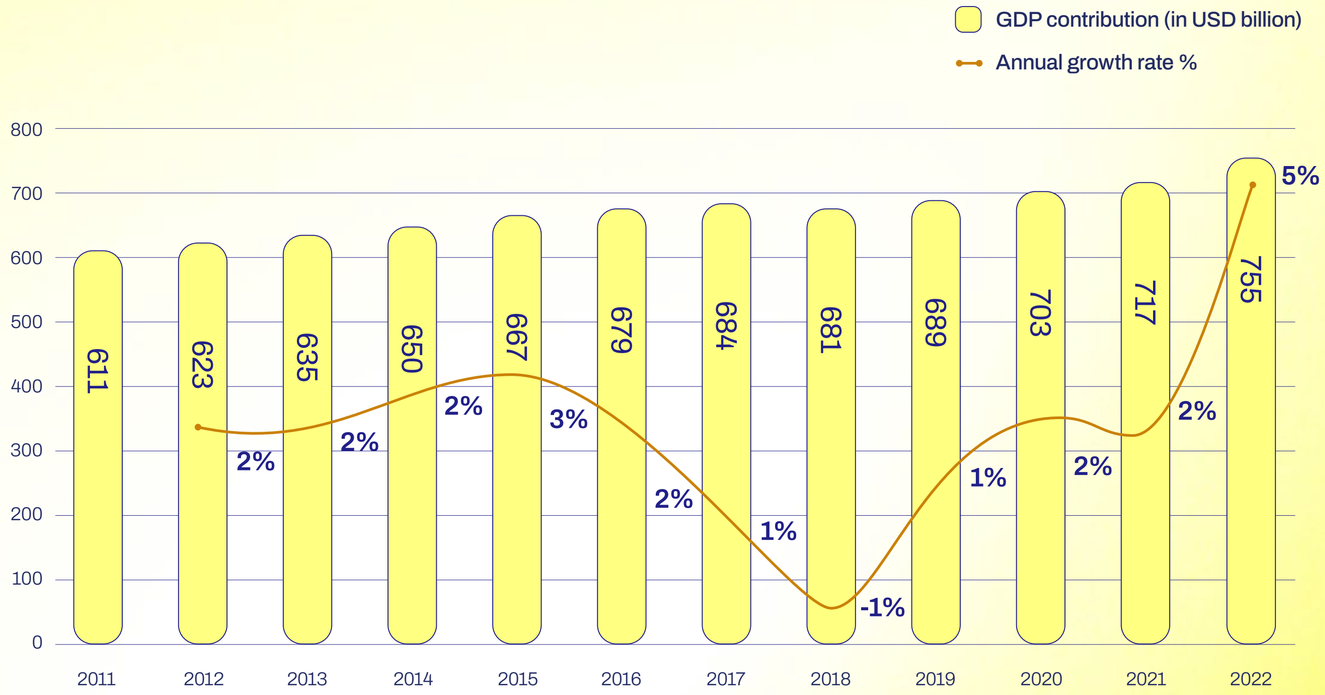


Figure 20: Direct GDP contribution (yellow bars) and annual growth rate of the global pharmaceutical industry (orange line), 2011–2022

Abbreviations: GDP, gross domestic product

Source: WifOR Institute, 2024[225]

The industry's direct contribution amounted to USD 755 billion, representing 0.7% of the global GDP or roughly equivalent to Switzerland's GDP in 2022.

4.2 Contribution to employment

Pharmaceutical industry operations support the global workforce. In 2022, the pharmaceutical industry supported the **employment of 74.9 million people globally**. Out of these, 7.8 million jobs were employed directly in the industry, 44.7 million indirectly, and 22.4 million through induced effects along the supply chain (Figure 21) (spillover effects include employment enabled along the global value chains and induced by household income spent in the wider economy). For every job directly created by the industry's activities, another (indirect and induced) 8.54 jobs were supported along the global supply chain.[225]

Of the 7.8 million people directly employed by the pharmaceutical industry in 2022, approximately 14% (1.1 million) are involved in R&D activities. This marks a substantial 175% increase in R&D employment in the pharmaceutical industry compared to 2014 (0.39 million people). Workers engaged in R&D activities include highly trained researchers and specialists with technical experience and training.[225]

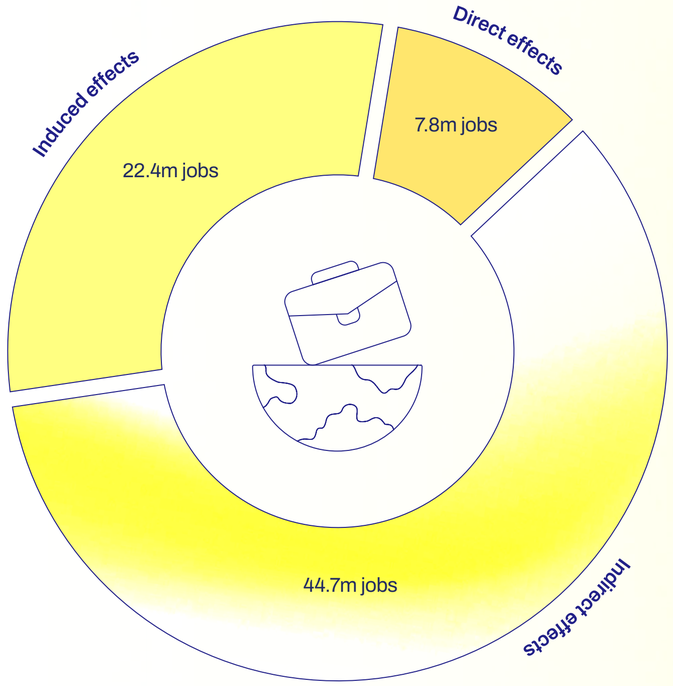


Figure 21: Direct and spillover employment effects of the global pharmaceutical industry, 2022

Source: WifOR Institute, 2024[225]

Conclusion

The pharmaceutical industry is unlike any other: its innovations can prolong and save lives. The industry operates in complex environments, forming trusted partnerships with a wide range of stakeholders to make this possible. A high level of integrity and trust is a precondition to ensuring ethical innovation and scientific progress.

Within the innovation ecosystem, pharmaceutical companies take the necessary risks to advance basic research into innovative medicines and vaccines. Pharmaceutical companies continuously invest in R&D, which leads to breakthrough innovations and continuous improvements to existing medicines. Pharmaceutical innovation requires significant expertise, long-term commitment and investments, and IPRs are crucial to protect innovations and incentivize the risky R&D investments that drive continual innovation.

Pharmaceutical innovations enable advancements in global health progress, allowing people to live longer and healthier lives. Medicines and vaccines are valuable from health, social, and economic perspectives. They allow individuals to actively participate in society, ensuring productivity and contributing to economic growth. Despite this being key to society, access to medicines and vaccines remains unequal around the world. Barriers to achieving equitable patient access to medicines in LMICs are complex, multi-faceted, and may be linked to regulatory processes, procurement systems, funding, distribution, health service delivery, and capacity.

Despite substantial progress in health, global challenges such as NCDs, ageing populations, AMR, climate change, and pandemics remain. Factors such as urbanization, conflicts, and displacement of people can aggravate these challenges. Addressing these complex issues requires action from different stakeholders. Pharmaceutical companies are making efforts to tackle these challenges in partnership with the global community.

As pharmaceutical companies continue to invest substantially in pharmaceutical R&D to bring new medicines and vaccines to market and improve health outcomes, their activities continue to have positive impacts of the global economy and workforce.

Acronyms

AI	artificial intelligence
AIDS	acquired immune deficiency syndrome
AMA	African Medicines Agency
AMR	antimicrobial resistance
ART	antiretroviral therapy Bio
ATMPs	advanced therapy medicinal products
CAR-T	chimeric antigen receptor T
CRISPR	clustered regularly interspaced short palindromic repeats
CVDs	cardiovascular diseases
DAAs	direct-acting antivirals
DCTs	decentralized clinical trials
DNA	deoxyribonucleic acid
EU	European Union
FDA	Food and Drug Administration
GDP	gross domestic product
GLP-1	glucagon-like peptide 1
HCV	hepatitis C virus
HICs	high-income countries
HIV	human immunodeficiency virus
HPV	human papillomavirus
ICH	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
IFPMA	International Federation of Pharmaceutical Manufacturers and Associations
IP	intellectual property
IPRs	intellectual property rights
LMICs	low- and middle-income Countries
mAbs	monoclonal antibodies
ML	machine learning
MPP	Medicines Patent Pool
mRNA	messenger ribonucleic acid
NASs	novel active substances
NCDs	non-communicable diseases
NRAs	National Regulatory Authorities
NTDs	neglected tropical diseases
OECD	Organisation for Economic Co-operation and Development
OHE	Office of Health Economics
PDPs	product development partnerships
PrEP	Pre-Exposure Prophylaxis
PROs	patient-reported outcomes
R&D	research and development
RNA	ribonucleic acid
RSV	respiratory syncytial virus
RWD	real-world data
RWE	realworld evidence
SCD	sickle cell disease
SDGs	Sustainable Development Goals
SMEs	small- and medium-sized enterprises
TB	tuberculosis
UHC	universal health coverage
US	United States
VC	venture capital
WHO	World Health Organization
WIPO	World Intellectual Property Organization

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