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Enabling innovation: The R&D ecosystem for medicines and vaccines

The research and development (R&D) ecosystem is undergoing rapid transformation. Decisive policy action is critical to sustain innovation that improves people's lives.

R&D is the engine transforming health outcomes for people, economies, and societies

Investment in the R&D of innovative medicines and vaccines has driven unprecedented progress in health, economic growth, and social well-being. For instance, around 70% of gains in people living longer in high-income countries can be attributed to new medicines.[1] Between 2007 and 2017, a subset of HIV and breast cancer treatments collectively led to 2 million additional healthy life years for people in the European Union (EU) and EUR 27 billion in productivity gains.[2] Global immunization has saved an estimated 154 million lives, averaging six lives saved every minute for the past 50 years; new data show that immunizing adults can generate returns to society up to 19 times greater than the original investment.[3 4]

New breakthrough therapies offer hope to millions of people worldwide. Over 940 novel active substances were launched globally between 2004 and 2023.[5] And in 2025, over 12,900 medicines were in clinical development globally, with three-quarters dedicated to non-communicable diseases (NCDs).[6]

70%
Around 70% of gains in people living longer in high-income countries can be attributed to new medicines

154m
Global immunization has saved an estimated 154 million lives

USD 227b
In 2022, the pharmaceutical industry's R&D activities contributed USD 227 billion to GDP globally

12,900
Over 12,900 medicines in clinical development globally in 2025

The innovative pharmaceutical R&D sector is a major driver of medical innovations that deliver economic value. In 2022, the pharmaceutical sector's R&D activities alone contributed USD 227 billion GDP globally, 30% of its direct contribution to the world economy. Of the 7.8 million people directly employed by the pharmaceutical industry, over 1 million are involved in R&D activities, fostering high-skilled employment and economic growth.[7]

Despite this health and economic progress, significant challenges remain, requiring continued commitment to deliver innovation. Around one-third of the global population lives with an NCD such as cancer, diabetes, heart disease, and lung disease.[6] These NCDs accounted for 75% of global mortality in 2021.[8] In the same year, lower respiratory tract infections were the fifth most common cause of death.[9] At least 90% of all rare diseases lack an approved treatment.[10]

The R&D ecosystem: Complex and ever evolving

Delivering innovation requires a thriving and sustainable R&D ecosystem where all stakeholders work in concert to deliver benefits to people and society. Governments, regulators, patients, academia, innovative pharmaceutical companies, technology and biotech companies, and other investors (for example, venture capitalists) all play complementary roles (Case study 1). Innovation ecosystems adapt as new technological and economic opportunities emerge. Today, advances in AI, machine learning, and analytics are reshaping R&D and elevating data and technology firms as critical partners in transforming science into promising medicines and vaccines.

These stakeholders work within an ever-evolving framework of policies, regulations, and incentives, creating an R&D ecosystem that is complex and interdependent (Figure 1). The roles of stakeholders in the R&D ecosystem continuously develop to reflect changes in science, technology, policy, and global market dynamics. Organizations increasingly engage in cross-sector partnerships early, rather than operating in silos (Case study 2). As a result, the boundaries between sectors are becoming less distinct, with new partnerships and hybrid organizations emerging and reinforcing interdependence between the pharmaceutical industry and partners. These voluntary arrangements are becoming increasingly important to ensure scientific advances are translated into health technologies that bring meaningful benefits to people worldwide (Case study 3).

Innovation cannot be taken for granted

Investing in R&D is a risky endeavor, marked by high failure rates and long, costly development timelines. New technological approaches such as gene therapy take decades to develop. AI is already accelerating several parts of the R&D process, particularly in discovery and data analysis. However, pharmaceutical R&D remains inherently time-consuming, as key stages of clinical development, manufacturing scale-up, and regulatory review must meet rigorous evidence and quality standards to ensure the safety, efficacy, and reliability of new medicines and vaccines.

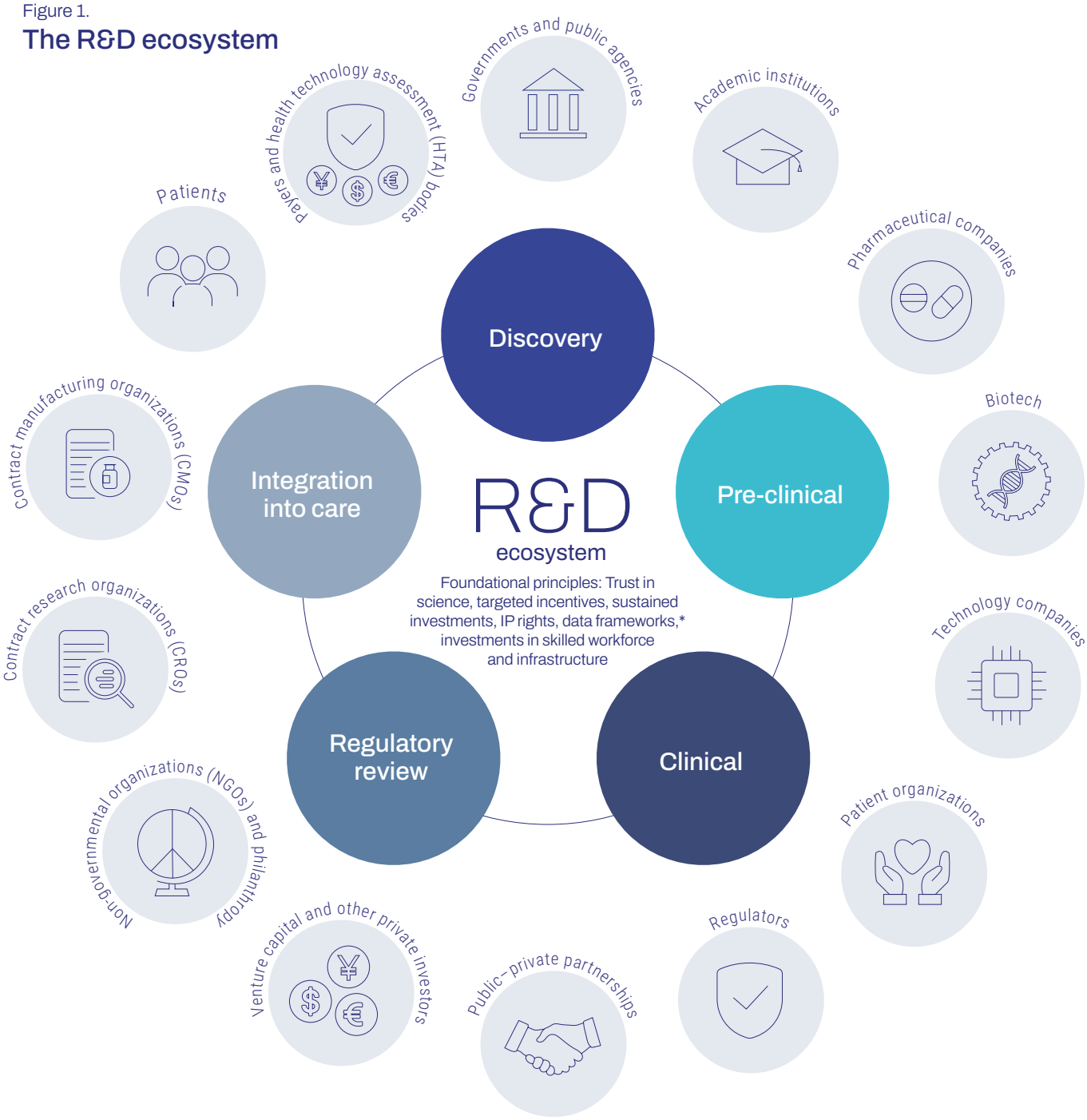
Global health innovation systems are under growing economic and geopolitical pressure. Global innovation capacity is shifting, with countries such as China rapidly expanding their R&D and manufacturing capabilities, and with tougher selection at every stage of development.[11,12] Geopolitical fragmentation, pressure to weaken intellectual property (IP) protections, vaccine hesitancy, reduced public funding for science, and declining trust in science all shape where public and private investment flows, how collaborations form, and how innovation ultimately reaches patients.

The future of innovation requires shared responsibility for sustained investment across the R&D ecosystem. The pharmaceutical industry provides the majority of global R&D investment — with the top 50 companies spending USD 167 billion in 2022.[13] However, long-term public and philanthropic funding is also essential to sustain basic science research (Case study 4), particularly where research needs are the biggest. Growing pressures on public investment in research pose a threat to advancing science and delivering medicines and vaccines to people.

To sustain innovation, the R&D ecosystem needs to be more adaptive, globally connected, technology enabled, and underpinned by a skilled workforce. This, in turn, requires the right legal, policy, and investment conditions so innovation can be delivered to people at pace and at scale.

Figure 1.

The R&D ecosystem



The pharmaceutical industry is a critical partner along all phases of what IFPMA refers to as the Innovation Development and Access Pathway.[15] It provides scientific, clinical, and operational expertise to drive health products' discovery and advance them through late-stage development, regulatory approval, market launch, and manufacturing — all necessary steps to reach the people who need medicines and vaccines.

* The nature and use of data in health are large. A description of these different types of data and their interlinkages is available here: International Federation of Pharmaceutical Manufacturers and Associations. 2026. International data flows: Enabling data-driven, patient-centric innovative pharmaceutical research and development (R&D).[14]

Making innovation possible: Addressing challenges and seizing opportunities across the R&D ecosystem

Discovery

Understanding disease biology and finding potential new treatments

Basic research generates new knowledge about mechanisms of action for diseases and understanding of biology of the human body. Early-stage research identifies potential biological targets and compounds, but also antigens/pathogens, and selects appropriate platform technologies to prevent, treat, or potentially cure a condition.

> 10,000
compounds screened and evaluated[16]

ROLES PLAYED BY KEY ACTORS

1	2	3	4	5	6
Governments and public agencies	**Academic institutions / Pharmaceutical companies / Biotech / Technology companies**	**Technology companies**	**Patient organizations**	**Regulators**	**Public–private partnerships**
Fund early-stage research, shape incentives[17]	Conduct basic and early-stage research[18]	Help accelerate target identification/validation, early-stage compound discovery, and molecule design	Guide research prioritization and study design[19]	Set standards and requirements for conduct of clinical research[20]	Allow resources, know-how, and risks to be shared[21]

CHALLENGES	SOLUTIONS
Incomplete biological understanding: Despite progress, the lack of deep understanding of human biology and physiopathology in some therapeutic areas (for instance, Alzheimer's disease) is slowing down innovation.[22 23]	**Strengthen investments in discovery science:** Increase long-term investment in foundational research to reinforce scientific knowledge and accelerate identification of optimal biological targets.
Weak incentives for investment, particularly in some areas of unmet need: Misalignment between commercial viability and societal needs constrains investment where innovation is most needed.[17]	**Strengthen incentives:** Where there is market failure, use targeted "push and pull" incentives — such as secured public funding of research, economic or tax incentives, and clear innovation policies — to attract R&D investment to societal priorities.[17 24]

† AI may help to accelerate this time.

Pre-clinical

Establishing early evidence

In the pre-clinical phase, potential medicines are tested using a combination of computer-based tools, laboratory testing, and animal studies. This builds early evidence that medicines are likely to be safe and effective before they are tested on people. For vaccines, this stage focuses on showing that early vaccines design can safely trigger an immune response and can be produced at scale, helping to confirm that a vaccine candidate is viable before clinical trials begin.

250
compounds tested[13]

ROLES PLAYED BY KEY ACTORS

1	2	3
Biotech / Pharmaceutical companies / Technology companies	**Venture capital and other private investors**	**NGOs and philanthropy**
Conduct research[25]	Provide funding to biotech companies[25]	Provide grants for early research, especially in areas that are underserved by traditional funding[26 27]

CHALLENGES	SOLUTIONS
High failure rates: Vast numbers of potential compounds (including vaccines) are explored, but only a few progress through initial safety analyses; fragmented access to high-quality data results in low success rates and wasted resources.[28]	**Enable smarter discovery:** Enable data-sharing environments and AI-enabled analytics for better selection of early compound, as well as strong translational capabilities that move a compound from lab discovery into clinical development, manufacturing, and real-world use.[29 30]
Reliance on animal models introduces translational risk: Animal models offer imperfect human predictivity, contributing to high attrition of candidate compounds.	**Leverage new approach methodologies (NAMs):**[§] Integrate validated NAMs as superior human-relevant predictors, reducing animal use.
Limited IP protection: Without strong incentives and effective IP protection and enforcement, R&D investment is discouraged and innovation chains weaken.[18]	**Protect innovation:** Strong IP rights reward risk-taking, attract investment, enable partnerships, and ensure returns are reinvested into future R&D as ideas move from lab to market.[18]

‡ AI may help to accelerate this time.

§ NAMs are advanced testing methods that use computer models and advanced laboratory systems to generate more predictive, human-relevant evidence, improving how potential medicines and vaccines are evaluated.

Clinical development

Demonstrating benefit

Clinical trials are essential to establish whether new medicines and vaccines are safe, effective, and deliver meaningful benefits to people.[11]

Their design and conduct are governed by rigorous regulatory and ethical standards, ensuring the generation of robust evidence to support the use of medicines and vaccines in clinical practice.

Fewer than
10 candidates
investigated[31]

ROLES PLAYED BY KEY ACTORS

1	2	3	4	5
Pharmaceutical industry	**CROs**	**CMOs**	**Patient organizations**	**Patients**
Fund and conduct trials[25]	Manage operational, clinical, and regulatory aspects of trials[32]	Help manufacture the substances used in trials[32]	Raise funds and advocate for research; directly sponsor or conduct trials[33]	Participate in trials

CHALLENGES	SOLUTIONS
Slow and complex trial delivery: Lengthy approval and recruitment periods delay clinical trial progress,[24] especially for large-scale, multi-country trials with operational and regulatory complexities.	**Faster pathways:** Efficient and aligned regulations and swift access to advanced technologies (such as AI-powered diagnostics) can accelerate enrollment and delivery, particularly for trials in precision medicine.[24]
Clinical data issues: Absent, inconsistent, or weak regulatory data protection (RDP)[‖] in some countries, and barriers to cross-border data transfer, hinder global R&D.	**Robust data policy framework:** Forward-looking data regulation and policy, including RDP, that both support innovation and protect people will facilitate clinical trials and enable better health outcomes.
Regional infrastructure gap: Limited healthcare infrastructure impacts trial delivery in some parts of the world.[24]	**Build trial capacity:** Invest in a skilled workforce and fit-for-purpose trial infrastructure to sustain clinical research capacity, and explore innovative trial designs (for example adaptive, decentralized, AI-enabled trials).[24]
High-risk, costly manufacturing investments: Early development for complex biologics requires significant upfront investments in production capacity, while changes to manufacturing processes later in development can be complex due to quality and regulatory requirements.	**Early and predictable demand signals and funding:** Complex molecules innovation depends on early, sustained, and predictable demand and investments to de-risk scale-up and enable viable manufacturing pathways.

‖ RDP is a time-limited period during which competitors cannot rely on the originator company's pre-clinical and clinical test data to support approval of follow-on products.[34]

Regulatory review

Evaluating evidence for the approval of new medicines and vaccines

Approval requires rigorous evaluation of the quality, safety, and effectiveness for new medicines and vaccines.[13] Regulatory oversight is also needed to ensure quality is maintained in the transition from small-scale clinical production to large-scale commercial manufacturing.[35]

1–2
vaccine or medicine candidates approved[36¶]

ROLES PLAYED BY KEY ACTORS

1	2	3
Regulators	**Pharmaceutical companies**	**Patient organizations**
Conduct assessments that determine approval of new vaccine or medicine[17 20]	Navigate regulatory processes and submit evidence to gain approval[25]	Share patient views on the benefits and risks of the medicine or vaccine[19]

CHALLENGES	SOLUTIONS
Fragmented regulatory requirements: Evidence requirements, processes, and governance frameworks that differ between countries increase cost and uncertainty, and delay access for people.[37]	**Promote regulatory reliance and convergence:** These are the key strategies for strengthening predictable regulatory systems by optimizing resources, reducing duplication, and accelerating access to high-quality medicines.[38]
Weak regulatory data protection: Inadequate protection enables reliance on originator data without appropriate trials, raising safety and quality concerns and undermining collaboration between innovative and generic companies.	**Strengthening regulatory data protection:** Robust and enforceable protections support a rigorous regulatory process, safeguard patient data, facilitate collaboration between innovators and generics developers, and help maintain high standards of safety, quality, and efficacy.

¶ The R&D process is cyclical. After a medicine is approved, researchers often look for new ways it can help people, revisiting earlier steps to test and expand potential uses.

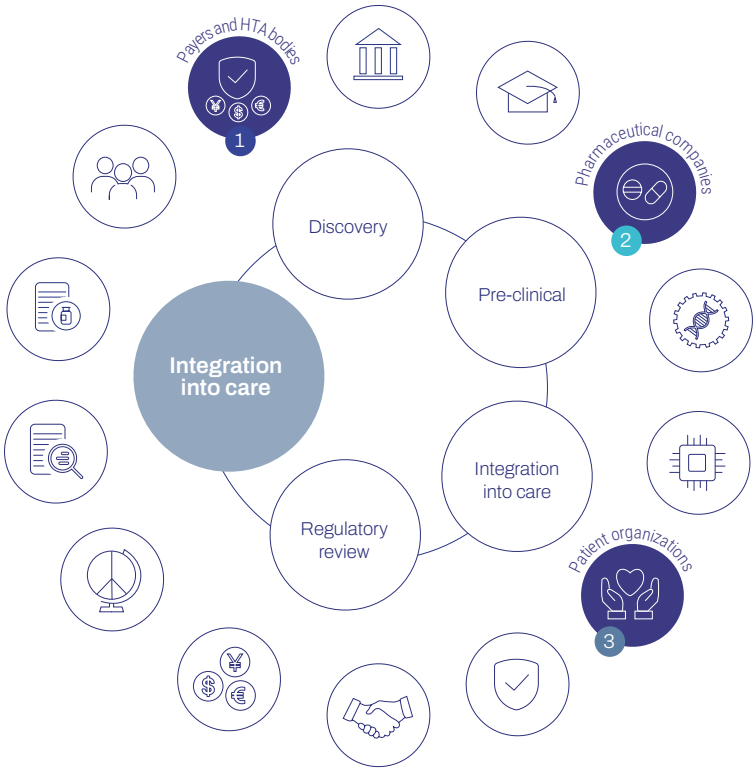
Integration into care

Delivering innovation to people

Following approval, medicines and vaccines undergo further evaluation to determine at what price they will be made available and to what extent they will be funded within health systems.[25] Medicines also need to be fully integrated into care pathways, with appropriate links to diagnosis and follow-up care.[39]

For vaccines, effective integration into care depends on early and reliable demand planning, giving manufacturers the visibility needed to align long-term investment, manufacturing capacity, and supply with immunization program needs and coverage goals.

Monitoring of vaccines and medicines when used in clinical practice allows us to gather real-world data on safety and effectiveness.[13] Post-approval research is key to exploring new indications and target populations, as well as enhancing medicines themselves (for instance, through improved routes of administration).



ROLES PLAYED BY KEY ACTORS

1

Payers and HTA bodies

Assess economic impact and added clinical value to determine funding/reimbursement[17]

2

Pharmaceutical companies

Provide evidence of clinical and economic value to inform recommendations and support funding/reimbursement decisions[25]

3

Patient organizations

Provide HTA, public health, and reimbursement agencies with patient perspectives, and support people with updated information on available treatments[19]

CHALLENGES	SOLUTIONS
Delayed uptake and undervaluation: Proven innovations often take years to reach people, partly due to reimbursement and HTA frameworks that insufficiently consider long-term societal benefits, and the connection between a reimbursement decision and resource allocation.[40]	**Reward full value and support timely uptake:** Horizon scanning and value frameworks that consider broader societal impacts can enable the appropriate investment, timely adoption of new therapies, and their effective use in clinical practice.[38 40]
Fragmented care pathways: Poorly integrated care pathways and immunization programs — combined with misaligned funding and limited access to prevention, diagnosis, and treatment — disrupts continuity of care for people and limits timely, equitable access to new treatments.	**Align incentives across the market:** Funding/reimbursement decisions for medicines, vaccines, and diagnostics must recognize the benefit to people and society through reimbursement frameworks and long-term demand planning that enable a sustainable innovation ecosystem and manufacturing capacity investments.
Erosion of effective market exclusivity: Long development timelines erode the period of market exclusivity for treatments; the entry of generic medicines diminishes returns, threatening the viability of innovation.[18]	**Preserve innovation incentives:** A balanced approach combining IP — including patent incentives, such as term extension — and RDP, alongside voluntary and flexible access approaches, helps facilitate access to care while safeguarding the R&D ecosystem.[17]
Manufacturing and supply vulnerabilities: Complex production and fragile global supply chains that are vulnerable to political and policy changes (for instance in the areas of trade, industrial, or health) can limit timely access to people.[41 42]	**Strengthen manufacturing resilience:** Investing in advanced manufacturing capacity, viable procurement mechanisms, secure and interconnected supply chains, and reliable open trade policies will help ensure timely and continued manufacturing and supply.[24 42]

Conclusion

Scientific breakthroughs are paving the way for transformative medical innovation, but the future of health innovation depends on the choices governments make today. Unlocking the value of the R&D innovation ecosystem relies on governments creating the conditions that enable and promote innovation. These include forward-looking policies, stronger recognition of the value of innovation, economic incentives in non-commercially viable disease areas, as well as policies that support cross-sector collaboration, open trade, data sharing, and investment in talent and infrastructure across the health system.

As AI increasingly shapes the medicines' life cycle and regulatory decision-making, robust governance is essential to secure patient privacy and system integrity. At the same time, strengthening trust in science and in vaccine confidence, as well as sustaining public investment in science, remains essential to ensure the next generation of medicines and vaccines supports healthier populations, stronger economies, and more resilient societies.

CASE STUDY 1.

The potential of GLP-1 therapies to treat multiple conditions

The development of GLP-1 therapies is a landmark achievement and a powerful example of how deep scientific research and cross-sector partnerships can lead to innovative medicines.

It also demonstrates how a single scientific insight can be scaled to treat a spectrum of chronic diseases. Originating in the 1980s with the academic discovery of the GLP-1-peptide in gut-mediated insulin production signaling, the insight later evolved into an understanding of the gut–brain–organ axis.[43]

Transforming this knowledge into treatments required a seamless, high-functioning ecosystem.

Academic scientists mapped the biology, biotechnology innovators engineered the molecule to improve its stability over time, and the pharmaceutical industry conducted multi-year clinical trials — collaborating closely with regulators on robust design and safety assessments — to demonstrate the benefits of GLP-1 treatments in metabolic disorders.[44-46] These include heart, kidney, and liver diseases.[45 47 48]

These efforts resulted in treatments approved for type-2 diabetes in 2005, and weight management in 2014.[44 47] Other indications for obstructive sleep apnea, cardiovascular disease, kidney disease, and metabolic dysfunction-associated steatohepatitis (MASH) have followed, and ongoing trials are exploring other indications such as osteoarthritis, some cancers, and musculoskeletal conditions.[47-49]

CASE STUDY 2.

Hepatitis C: The impact of sustained, multi-sectoral investment

Sustained basic and translational research over two decades transformed hepatitis C from an often life-threatening, progressive disease into the first chronic viral infection that can be cured in more than 95% of patients.[50] It enabled researchers to map the hepatitis C genome and identify key viral enzymes, paving the way for virus-targeted therapies.[50]

Coordinated efforts between academia, industry, and regulators enabled the development of direct acting antivirals (DAAs), the first curative treatment for hepatitis C, and governments played a key role in building DAAs into their national plans to secure sustainable funding for patients.[51]

CASE STUDY 3.

Antimicrobial resistance: Stakeholder roles evolve where market incentives are weak

Gaps in market incentives can leave critical areas of unmet need — such as antimicrobial resistance — underserved, requiring alternative models of collaboration across the R&D ecosystem. The Global Antibiotic Research and Development Partnership (GARDP), a non-profit, was established to help address these gaps.[52] It partners with academics, biotechs, and pharmaceutical companies to develop new and effective antibiotics to protect adults and children from the rise and spread of drug-resistant bacterial infections.

GARDP and Innoviva Specialty Therapeutics (IST), a subsidiary of Innoviva, secured approval from the US Food and Drug Administration for a new antibiotic in late 2025. GARDP led the phase III trial after an early agreement with the biotech Entasis Therapeutics; Innoviva acquired Entasis in 2022 and was actively engaged in the development and regulatory process. GARDP is also working to expand the availability of other antibiotics in low- and middle- income countries, for example, through a licensing collaboration with Shionogi, Bugworks, and Debiopharm, and separate memorandums of understanding with companies such as Lixa, MSD, Roche, and Tamrisa.

CASE STUDY 4.

Vaccine platform diversity: Building readiness for future health threats

Decades of investment in diverse vaccine platform** technologies, delivery systems, and translational research have strengthened preparedness for both endemic and emerging infectious diseases. Depending on the target pathogen, different vaccine platforms can be used to elicit an immune response, with each platform offering distinct advantages and constraints depending on the biology of the pathogen, the desired immune response, and population needs.

The rapid development of COVID-19 messenger ribonucleic acid (mRNA) vaccines illustrates how sustained investment in a specific platform, combined with public support, biotech innovation, and industrial capability, enabled progression from viral genome sequencing to approval in under a year.[53] While mRNA platforms proved particularly well suited for certain pathogens, maintaining a diverse portfolio of vaccine platforms remains critical to manage risk and to ensure readiness across a wide range of pathogens, populations, and public health needs. These platforms continue to be applied and adapted across multiple diseases.

** Vaccine platform technologies are reusable vaccine development systems that can be adapted to target different diseases using the same core technology.

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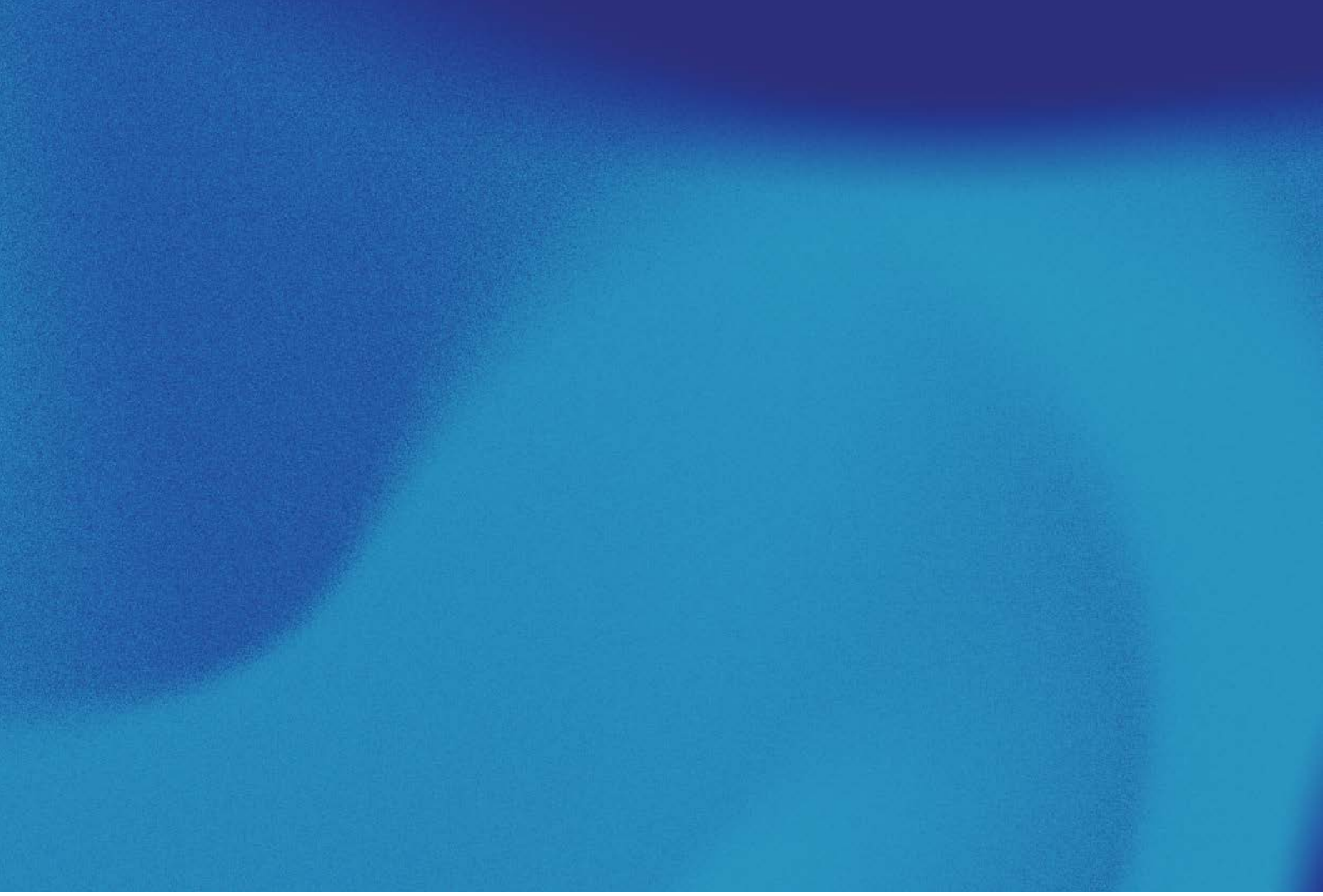

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About IFPMA
IFPMA represents the innovative pharmaceutical industry at the international level, engaging in official relations with the United Nations and multilateral organizations. Our vision is to ensure that scientific progress translates into the next generation of medicines and vaccines that deliver a healthier future for people everywhere. To achieve this, we act as a trusted partner, bringing our members' expertise to champion pharmaceutical innovation, drive policy that supports the research, development, and delivery of health technologies, and create sustainable solutions that advance global health.

For more information, visit https://www.ifpma.org/.