IFPMA

International data flows: Enabling data-driven, patient-centric innovative pharmaceutical research and development (R&D)

Data-driven R&D is important for patients, populations, and health systems

Every patient's experience – getting a diagnosis, starting treatment, living with side effects, seeing what works and what does not – generates information that can help improve their care and care for others. Collected and used responsibly with the appropriate levels of informed consent, this information helps pharmaceutical researchers understand diseases better, enabling the development of new medicines and vaccines for people who need them. This information is an example of one type of real world data that is important for advancing healthcare.

Pharmaceutical companies use this type of real world data, among others, to ensure and improve safety, efficacy, and effectiveness of care for patients, populations, and health systems. More and better data that is representative and used responsibly helps develop better health solutions. Understanding patient and population health and leveraging the growing scientific knowledge base are some of the most meaningful ways of informing impactful pharmaceutical R&D and bringing us closer to addressing present and future clinical need.

Different types of data and why they matter for appropriate use and governance

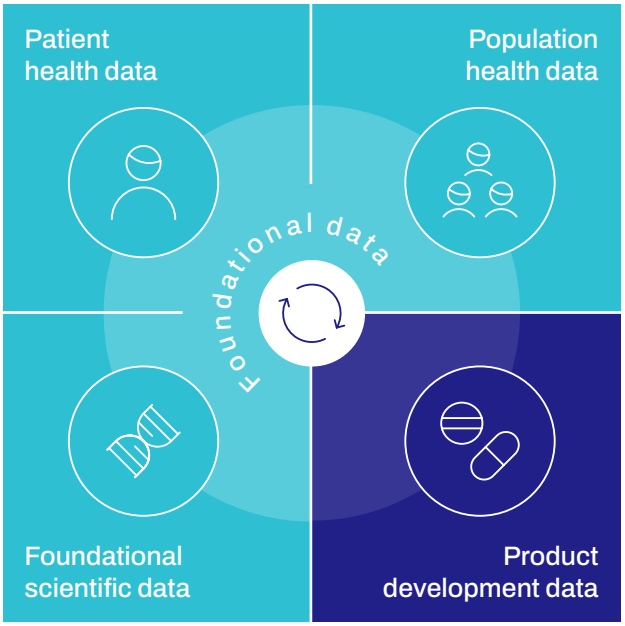
Global pharmaceutical R&D leverages many different types of data, including real world patient experiences, health system information, and foundational scientific data. When these data sets are high quality, secure, and responsibly shared and used, they can shorten the time it takes to develop new medicines and vaccines, improve safety monitoring, and support more effective and personalized care for patients. Growing technological capability, including the use of AI-enhanced processes in relation to data analysis and R&D, can further lead to improved health outcomes.

While all pharmaceutical R&D is underpinned by data, importantly, different types of data are and should be treated differently. Data governance and use frameworks need to account for the fundamental differences between data sets – in terms of their sources, utility, and sensitivity – to protect individual patients, populations, and health systems, while encouraging innovation.

For instance, some data, such as the data generated by innovators in the course of R&D and clinical studies, is proprietary and protected by intellectual property rights (IPR), including trade secret laws and regulatory data protection (RDP) systems. These mechanisms are necessary to enable the large investments needed to sustainably generate and use that data to develop new medicines and vaccines. Other types of data, such as those collected by health systems, do not usually implicate the same considerations.

In all cases, pharmaceutical companies comply with rigorous standards, rules, and regulations in our use of human data, whether such data is part of a proprietary clinical study or housed outside of the industry. In the case of individuals – especially for sensitive personal data – this may mean data de-identification such as anonymization or pseudonymization.

Appropriate data governance is essential for R&D, disease management, and healthcare delivery. But today, pathways for access to and use of foundational data are not always clear, and barriers to appropriate international data flows are increasingly common – including for patient health data and genetic sequence data. This risks limiting basic research and delaying pharmaceutical innovation, putting health security at threat and standing in the way of better patient outcomes, stronger health systems, and economic growth.



→ Different types of data have different origins and are not all used in the same way, nor should they all be treated the same. Some foundational data is personal and comes directly from individual patients, some from healthcare systems, and some represents foundational scientific knowledge, which can be from both human and non-human sources. All of these may be subject to distinct data governance and protection norms. Further, significant proprietary data is also generated by companies themselves, as part of testing, development, and monitoring activities to ensure patients and populations receive safe, effective, quality treatments and vaccines. Such proprietary data may be protected by IPR, including trade secrets and RDP, and confidential information.

Examples of data categories and uses in pharmaceutical R&D

Patient health data

Patient electronic health records (EHRs), patient registries, and administrative claims help us understand how people experience disease and treatment in real life, including benefits, side effects, and quality of life. These inputs are used to guide R&D priorities.

Population health data

Disease surveillance data for a human population or demographic can help elucidate unmet clinical needs and health system shortcomings to inform disease targeting in R&D.

Foundational scientific data

Data on human molecular structures underpinning disease such as genes (genomics) and proteins (proteomics) provides a comprehensive understanding of complex biological processes, which supports the development of targeted medical interventions that can cure, prevent, or intercept disease.

Non-human data from biologic and other sources also plays an important role – for example, pathogen Digital Sequence Information (DSI) helps prevent and tackle global health threats such as epidemics and pandemics.

In silico data

Computationally derived data at any stage of R&D helps transform data-based insights and accelerates product development – this can be via computer simulations or modelling, including using AI tools.

Non-clinical trial data

Non-clinical test data generated by initial lab trials is used for discovery, target validation, as well as to assess basic safety before proceeding with clinical trials in human patients.

Clinical trial data

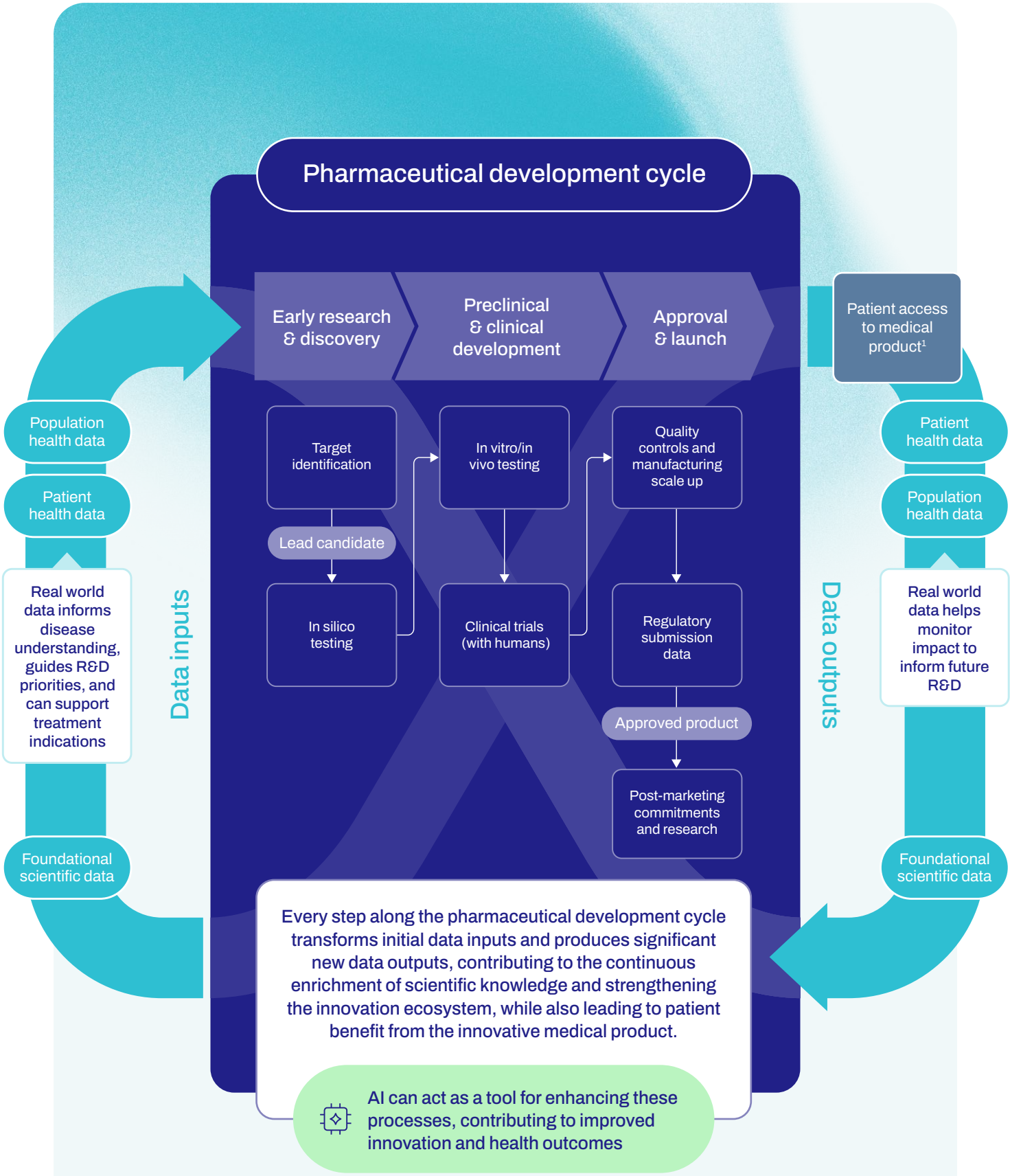
Clinical trial data from humans is generated to ensure product safety, efficacy, and effectiveness, while protecting patient privacy.

CMC/quality data

Data obtained in pharmaceutical product analysis to demonstrate alignment with regulatory Chemistry, Manufacturing, and Controls (CMC) frameworks, ensuring patients receive safe, quality-made products.

Post-marketing data

Data generated by companies in the study of effects of treatments and vaccines in the population, as well as surveillance monitoring data, including to inform future R&D and improve health systems performance.



1. See also IFPMA (2025). The innovation development and access pathway. Available at https://www.ifpma.org/publications/the-innovation-development-and-access-pathway-a-holistic-approach-to-accelerating-access-to-innovative-medicines-and-vaccines

Using data to develop life-saving medical innovations, enhance patient outcomes, and improve health systems

Pharmaceutical R&D is an intensely iterative and collaborative process that requires significant time, resources, and involves high attrition levels and uncertain outcomes[2] – only 0.01% of compounds synthesized in laboratories eventually reach the market[3]. Pharmaceutical companies constantly generate and transform data through our continuous R&D efforts, meaningfully contributing to expanding foundational scientific knowledge and strengthening the innovation ecosystem, even when product development fails.

The product development cycle spans early and preclinical research, clinical trials, regulatory approval, and launch. But the R&D process does not end there – after the product is approved and available to patients, continued understanding of its impact on patients, populations, and health systems is essential, including to guide further R&D efforts. These processes are guided by robust regulatory science and are governed by regulatory and other authorities.

Designing an international data policy environment fit for the future

Emerging technologies, new players, and emerging policies may significantly impact the current state of pharmaceutical R&D and redefine our data landscape and use cases. Creating the right international policy environment to sustain and foster this interconnected R&D ecosystem for the future requires understanding and respecting the different types and origins of data, as well as pharmaceutical industry inclusion in the data policy debate and design, especially as it evolves in response to the accelerating use of AI tools. Enabling the global flow of data for health R&D – that is, ensuring appropriate data use and sharing across borders with safety, quality, and corresponding protections – requires appropriate policy frameworks.

Depending on the type of data and the circumstances, the innovative pharmaceutical industry participates in a variety of structured data-sharing approaches across the R&D lifecycle, including pre-competitive collaborations, disease-specific platforms, and clinical research data-sharing initiatives[4]. These mechanisms and the appropriate sharing of some types of data with the research community support progress in health and scientific research and build trust, while respecting patient privacy, ethical standards, and the need to protect commercially sensitive information. Clear governance frameworks and appropriate protections help enable data sharing that delivers tangible benefits for patients and populations, while sustaining the investment and risk taking required in pharmaceutical R&D.

2. IFPMA (2026). Enabling innovation: The R&D ecosystem for medicines and vaccines. Available at https://www.ifpma.org/publications/enabling-innovation-the-rd-ecosystem-for-medicines-and-vaccines
3. IFPMA (2025). #AlwaysInnovating: Pharmaceutical Industry Facts & Figures. Available at https://www.ifpma.org/initiatives/alwaysinnovating-pharmaceutical-industry-facts-figures
4. See for example Vivli, Center for Global Clinical Research Data. Available at https://vivli.org and TransCelerate Biopharma Inc. Available at https://www.transceleratebiopharmainc.com

The innovative pharmaceutical industry focuses on delivering R&D to meet the medical needs of patients and populations of today and tomorrow. We rely on a data ecosystem that can support this mission and caution against overly prescriptive, hyper-localized policies, with requirements that risk impeding health innovation, limiting or delaying patient access, and undermining health security.

To fulfill the potential of data and new technologies in supporting the shared objective of improving patient lives and population health, it is vital that well-designed systems are put in place. We provide here a guiding vision for a forward-looking data ecosystem to start the conversation and help drive progress toward that common objective.

The international data ecosystem

Improving patient outcomes and population health by driving cooperation to:

Ensure data security and quality

Drive efficacy and impact

Enable international data collaboration

1. Enhance public understanding of the benefits of responsible health data sharing and building trust in the regulatory protections and guardrails for use of human data in pharmaceutical R&D with appropriate protections for individual patients.
2. Maximize the impact and benefit of health data with clear frameworks for secondary use (i.e., reuse), respecting intellectual property rights and protecting commercial R&D data to encourage innovation.
3. Strive for high-quality, representative health data by investing in health system data infrastructure, public health surveillance, and screening.
4. Ensure unhindered access to non-human foundational scientific data, including digital sequence information (DSI) from genetic resources.
5. Strengthen interoperability across health system and related infrastructures, with appropriate frameworks for cross-border data transfer.
6. Champion responsible and meaningful use of emerging technology and tools, including AI, by ensuring high-quality inputs, measuring impact, and by avoiding undue restrictions on its use with over-localized requirements.

Underpinned by responsible use of health data and technology[5]

This vision should be understood within a broader framework of shared ethical principles that guide the responsible use, governance, and sharing of health data.

5. See International consensus framework for ethical collaboration in health, principle no. 5: https://www.ifpma.org/publications/consensus-framework-for-ethical-collaboration and IFPMA (2021). Data Ethics Principles. Available at https://www.ifpma.org/publications/ifpma-data-ethics-principles

The innovative pharmaceutical industry stands ready to work closely with governments, regulators, patients, healthcare workers, academia, civil society, and other stakeholders toward an ecosystem that enables both academic research and private sector innovation to generate better health outcomes for all.

IFPMA International Federation of Pharmaceutical Manufacturers & Associations

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 ifpma.org