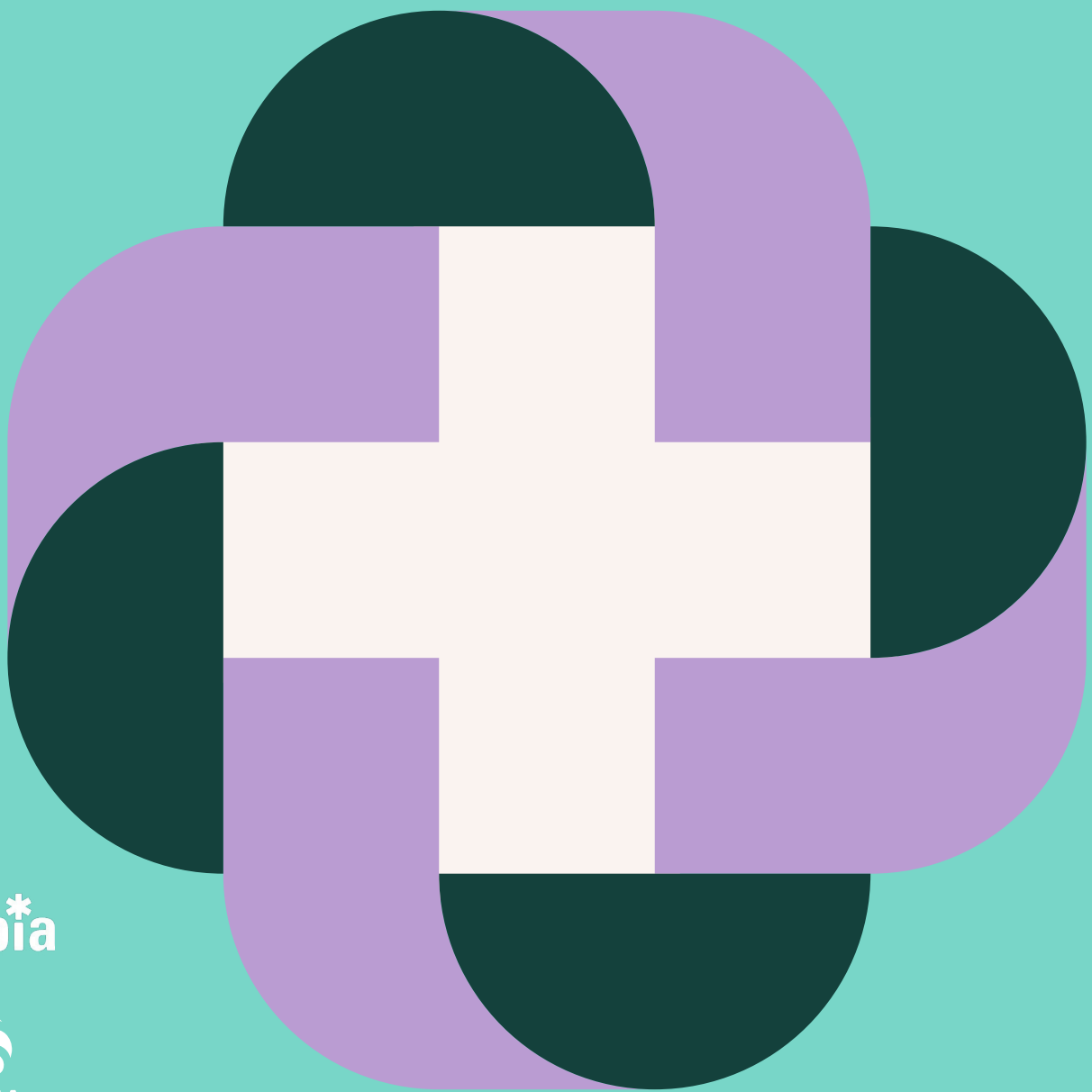


Biopharmaceutical
Industry

Global Policy Principles
on Digital Health



efpia*



IFPMA



JPMA

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Executive Summary

Today's global health challenges and priorities require innovative approaches, including digital health and data-driven solutions. These solutions have proven their real world value by helping to combat COVID-19.

At the same time, the pandemic has reinforced how critical it is to accelerate the digitalization of health systems around the world, and to have appropriate policies and resources that enable digital health benefits to reach all who need them.



Digital health technologies impact every aspect of the biopharmaceutical value chain, from drug discovery to clinical development through product launch to post approval surveillance and support for patients, caregivers, and healthcare professionals. The biopharmaceutical industry is investing in digital health to transform its work in development and commercial settings and enhance the contributions it makes to patients and health systems around the world.

Going forward, digital health can bring many benefits and opportunities, provided all health system stakeholders are able to overcome key challenges and barriers. In this regard, we need to ensure that the policies that have been deployed to address the COVID-19 pandemic will continue to support sustainable, patient-centric health systems in the future and combat the “double burden” of infectious and chronic, non-communicable diseases (NCDs).

The biopharmaceutical industry is committed to collaborating with other stakeholders to foster changes to policy environments that will deliver sustainable benefits to patients and health systems from digital health solutions.

Part 1

Today's global health challenges require innovative approaches, including digital health solutions, to address key priorities.



Today, the world faces a considerable array of global health challenges. These include a shifting disease burden (continuing rise of NCDs, double burden of infectious and chronic disease, and convergence of human and planetary health/climate-related health issues), continuing health inequalities in all countries around the world, a need to recover from the massive health and economic burden of COVID-19, preparations for future pandemics, and finding ways for health systems to get the most value from all the financial and human resources the world can muster.

THESE CHALLENGES REQUIRE ALL STAKEHOLDERS TO THINK AND ACT DIFFERENTLY.

We recommend that all stakeholders work together to embrace innovative approaches, including those enabled by digital health, to achieve the following priorities:

- Achieve greater health equity and make continuing progress towards the goal of improving equitable access to the health services that people need.
- Improve global health security by minimizing the danger and impact of public health threats, such as future pandemics, that endanger the health of populations.
- Foster appropriate collaboration between patients, healthcare providers, and other stakeholders to make meaningful progress toward patient-centered healthcare by understanding and addressing patients' individual values, needs, and experiences, and what is likely to result in positive outcomes that matter to patients.
- Facilitate innovation that enables the research, development, and delivery of more effective medicines to improve patients' lives.

If implemented properly, digital health solutions will help health systems overcome these challenges and achieve these priorities.

Part 2

Going forward, digital health will bring benefits and opportunities – provided stakeholders collectively overcome key challenges and barriers.

The use of digital health technologies brings many potential benefits and creates multiple opportunities for patients, health systems, and other stakeholders, including the biopharmaceutical industry. We believe there should be a strong alignment of interests

around promoting the uptake and dissemination of digital health solutions. To realize these benefits, all health system stakeholders need to work together to address barriers to the approval, funding, use, and uptake of digital health solutions.

BENEFITS/OPPORTUNITIES FOR PATIENTS AND OTHER HEALTH SYSTEM STAKEHOLDERS



Enhanced patient access, equity, and outcomes

- ↑ Empowered patients with greater self-care opportunities and improved outcomes that matter to them
- ↑ More personalized treatments to address patients' individual needs
- ↑ Improved healthcare and patient access in remote areas with isolated/vulnerable populations and a shortage of healthcare workers.



Enabling health system transformation

- ↑ As appropriate, new collaborative relationships between patients, healthcare professionals, the private sector, and other health system stakeholders
- ↑ Improved access to screening for proactive prediction and potential prevention of disease
- ↑ Improved health product surveillance and monitoring
- ↑ Improved patient health outcomes.



Improved healthcare quality and efficiency

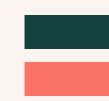
- ↑ Higher quality, more efficient healthcare
- ↑ Improved drug development processes (e.g., discovery, clinical research and product development).

CHALLENGES/BARRIERS FOR PATIENTS AND OTHER HEALTH SYSTEM STAKEHOLDERS (INCLUDING THE BIOPHARMACEUTICAL INDUSTRY)



Lack of fit-for-purpose healthcare policies

- ↓ Lack of harmonized regulations for use and regulatory acceptance of digital health technologies, including with respect to patient privacy and data security
- ↓ National "data localization" policies that restrict data flows/uses that would otherwise benefit patients and health systems
- ↓ Inconsistencies and limited interoperability between databases and systems
- ↓ Uncertain or ill-suited regulatory and funding pathways
- ↓ Existing/potential new restrictions on application of artificial/augmented intelligence (AI) in healthcare.



Concerns over ethical and equitable access issues

- ↓ Uneven access to digital technologies ("digital divide")
- ↓ Ensuring that patients are aware of and appropriately empowered to benefit from digital tools, particularly elderly and other vulnerable populations
- ↓ Unresolved questions around who decides what types of data should be collected, for what purposes, and how to maintain the security of data that are collected and used.



Challenges with change management and health system transformation

- ↓ High upfront costs and/or ongoing maintenance costs
- ↓ Potential inundation of healthcare professionals with huge amounts of data
- ↓ Ensuring that the health workforce is open to change and appropriately trained
- ↓ Difficulty measuring the impact of enabling tools versus current "base" interventions
- ↓ Ensuring that new entrants (technology companies and digital health start-ups) bring the required level of health system expertise and regulatory rigor.

Part 3

The biopharmaceutical industry is investing in digital health to address global health challenges.

Digital health technologies impact every aspect of the biopharmaceutical industry value chain, from drug discovery to clinical development through product launch and support for patients and healthcare professionals.

Ethical data use is crucial and requires consideration of the impact of data use on individuals and how such use aligns with human values, risks, and benefits. Therefore, the **IFPMA Data Ethics Principles**, encompassing the following aspects: a) Autonomy, b) Transparency, c) Data quality, d) Fairness & non-discrimination, e) Ethics by design, f) Responsible data sharing, and finally g) Responsibility & Accountability are needed to provide the foundation for ethical decision-making. This is with the interest and benefit of the individual as the primary focus, and with acknowledgement of the significant benefits to both individuals and society from data use.

BIOPHARMACEUTICAL COMPANIES ARE INVESTING IN DIGITAL HEALTH TO TRANSFORM THE CONTRIBUTIONS THEY MAKE TO PATIENTS AND HEALTH SYSTEMS IN VARIOUS WAYS →



Increasing patient engagement and support to improve outcomes

Companies are using digital solutions (websites, social media, mobile apps, call centers, emails and SMS/USSD messaging with local language capabilities), machine learning, and analytics, as appropriate, to engage patients and improve understanding of patient needs, behavior patterns, and health outcomes – while respecting applicable data privacy laws. This includes helping patients to (a) prevent the onset of disease; (b) identify and address symptoms early, access remote testing and obtain accurate diagnoses; (c) seek and find appropriate care; (d) understand coverage and reimbursement policies and available patient access programs; (e) adhere to treatment regimens prescribed by doctors; and (f) identify potential lifestyles and other changes to help manage chronic conditions via customized information flows and ongoing contacts with healthcare professionals as well as patients with similar conditions.



Enhancing drug/vaccine R&D and clinical research

Companies are enhancing drug and vaccine development processes with AI and advanced data analytics in many ways including by (a) discovering new disease targets to expedite and expand drug candidate selection capabilities; (b) predicting interactions between a compound and a target protein; (c) accelerating hypothesis generation and testing in research; (d) understanding human genetics; (e) curating and analyzing large volumes of data (including real-world data generated as part of routine clinical management) to accelerate drug discovery; (f) employing new ways to accelerate clinical trial enrolment and data collection by using digital tools to enroll appropriate trial participants and wearable devices to measure outcomes; and (g) enhancing diversity of patients in clinical trials.



Leveraging in-house expertise, global reach and new collaborations

Companies are enlisting qualified employees with relevant expertise (R&D, clinical research, data science, supply chain, regulatory approvals and post-market surveillance, navigating health systems, etc.) to build and support digital health approaches. This includes leveraging networks of relationships around the world to mobilize health system stakeholders and strengthen health systems. Companies are also building new approaches to digital health, including hiring executives responsible for digital technologies, and launching dedicated laboratories, innovation hubs, and multi-stakeholder partnerships to accelerate digital health development, deployment, and uptake.



Optimizing complex supply chain processes

Companies are using digital tools to optimize forecasting and planning, procurement and purchasing (upstream), manufacturing, warehousing and order/inventory management, procurement (downstream), wholesale distribution and delivery, reverse logistics and stock management, submissions for regulatory approvals and post-approval changes (where required), and overall supply chain management, such as ensuring a safe and secure supply chain.



Alleviating health system capacity constraints

Companies are supporting the use of appropriate remote consultation, care delivery, and monitoring to reach patients who are unable or unwilling to seek in-hospital care, and help providers overcome capacity constraints.



Enhancing communication, training, and education

Companies are supporting the increased use of digital and e-learning platforms to raise awareness, communicate on critical health issues, and provide training and education to healthcare professionals and patients as appropriate.

Part 4

The biopharmaceutical industry recommends new policies and resources to deliver sustainable benefits from digital health.

Global health stakeholders have acknowledged the need for new digital health-related policies. However, there are different views on how best to move forward. Enactment of new policies is primarily being led by national government agencies on a country-by-country basis. Trends in national policies center around (a) data security and data flows, (b) governance, (c) promotion of use, and (d) collaboration.

Looking ahead, sound national policies and international alignment are needed to ensure consistency and interoperability of policies and technology platforms.

THE BIOPHARMACEUTICAL INDUSTRY'S RECOMMENDATIONS INCLUDE THE FOLLOWING →



Build and implement digital health strategies and ecosystems

Appropriate policies and resources are needed to support national digital health strategies, including (a) nationwide digital literacy initiatives; (b) innovation ecosystems comprised of multi-stakeholder collaborations and frameworks that bring together expertise, ideas, assets, and resources; (c) change management in complex health systems; and (d) continuous learning initiatives such as regular multi-stakeholder events to build qualified workforces and review/debate new technologies and their implications.

National strategies should recognize the benefit of digital health solutions to improving patient care pathways, patient outcomes, and the economy.



Develop infrastructure and interoperability

Appropriate policies and resources are needed to support (a) improved connectivity (electricity, broadband, and mobile access) to ensure availability and affordability; (b) digital health platforms (“infostructures”); (c) harmonized, user-friendly electronic health records; and (d) data standards and interoperability between platforms.



Support collaborations and partnerships

Appropriate policies and resources are needed to support diverse stakeholder groups that are coming together to accelerate the launch of public-private partnerships that can overcome challenges and drive innovative digital health approaches.



Implement appropriate data governance including cross-system/cross-border data flows

Appropriate policies and resources are needed to enable effective, secure management of data to improve patients’ access to quality healthcare, patient health outcomes, and the development of new healthcare technologies, while recognizing the need for appropriate data protection requirements and the increasing role of individuals in managing access to their data. This includes a practical framework governing the exchange of digital health data across healthcare systems and national borders, an essential reality in an increasingly cloud-based world.



Create appropriate regulatory and payment pathways

Appropriate policies and resources are needed to ensure agile regulatory networks with requirements that are harmonized across national borders. Similarly, digital health solutions need to be appropriately valued and compensated.



Accelerate innovative research & development frameworks

Appropriate policies and resources are needed to support the development of digital endpoints and other tools to facilitate clinical research, AI/machine learning frameworks for medicine and vaccine R&D, genomic science-driven initiatives, and aligned, as well as adaptive, regulations.



Provide sustainable financing and incentives

Policies and resources are needed to incentivize and scale up common health platforms that will support the critical role digital health solutions can play in fostering pandemic preparedness and helping countries manage the “double burden” of infectious diseases and chronic/NCDs.

Case Study

Digital health solutions have proven their real world value by helping to combat COVID-19.

The COVID-19 pandemic has placed massive strains on health systems and healthcare workforces around the world, but it has also accelerated the adoption of innovative digital health solutions.

These steps towards the creation of a strong digital health ecosystem have been a critical success factor in the response to COVID-19. However, the pandemic has exposed significant limitations in the ability of health systems to collect, assess, integrate, share, and analyze high quality data, which has negatively impacted health system effectiveness and efficiency. Health systems stakeholders are recognizing the need to fill gaps in healthcare digitalization by enabling system-level changes to how they manage health data. Finally, societies need to address the digital divide to ensure that all people can access digital tools to improve their health.



- Vulnerable patients in areas that are remote or have a shortage of healthcare workers are benefitting from digital tools that are used to conduct community outreach and provide quality information and support.
- Digital health tools and data management systems are generating life-saving information that helps to manage the pandemic through symptom reporting, disease surveillance, and treatment response. These data can help optimize the health community response to COVID-19 and inform future pandemic preparedness needs.

FOR EXAMPLE →

- Digital tools have facilitated R&D for medicines and vaccines by accelerating the development process, helping clinical trials continue and opening the door for more diversity in trials.
- Public policies have greater use of telemedicine and other/remote consultation and monitoring tools to engage, diagnose, treat, and support patients. Providers have set up remote consultation tools (telemedicine) to triage patients so the healthy ones stay home, and HCPs can spend more time with patients who are most in need. Some payers are paying for remote consultation tools in a manner commensurate with what they pay for in-person consultations. As a result, patients/caregivers have more options for self-care and accessing healthcare, including getting advice, providing updates, and booking appointments online.

These approaches have reduced patients' potential risk of exposure to COVID-19, alleviated the burden on hospitals and HCPs, and supported the needs of patients who, due to health care worker shortages, have been unable to access needed care in-person.



Conclusion

Today's global health challenges and priorities require innovative approaches, including digital health and data-driven solutions. Going forward, digital health can bring many benefits and opportunities, provided all health system stakeholders are able to work together effectively to overcome key challenges and barriers. In a post-COVID era, a digital boom is occurring that requires appropriate policies and resources to ensure that digital health solutions will reach all those who can benefit from them.

The biopharmaceutical industry is investing in digital health to address the global health challenges of today and tomorrow. We are committed to collaborating with other stakeholders to implement changes to policy environments that will deliver sustainable benefits to patients and health systems from digital health solutions.

About the authors

EFPIA

The European Federation of Pharmaceutical Industries and Associations (EFPIA) represents the biopharmaceutical industry operating in Europe. Through its direct membership of 36 national associations, 39 leading pharmaceutical companies and a growing number of small and medium-sized enterprises (SMEs), EFPIA's mission is to create a collaborative environment that enables our members to innovate, discover, develop and deliver new therapies and vaccines for people across Europe, as well as contribute to the European economy.

→ efpia.eu

IFPMA

IFPMA represents R&D-based biopharmaceutical companies and associations across the globe. The biopharmaceutical industry's two million employees discover, develop, and deliver medicines and vaccines that improve the lives of patients worldwide. Based in Geneva, IFPMA has official relations with the UN and contributes industry expertise to help the global health community find solutions that improve health for populations around the world.

→ ifpma.org

JPMA

The Japan Pharmaceutical Manufacturers Association (JPMA) is a voluntary association comprising 73 research-oriented pharmaceutical companies (as of October 2021). JPMA, established in 1968 with the mission of "realizing patient-oriented healthcare," has been contributing to global healthcare advocacy through the development of innovative ethical drugs. We are engaged in various initiatives, such as solution of common issues in the pharmaceutical industry, activities to deepen understanding of pharmaceuticals and international collaboration with concerned parties. Especially, we are promoting sound development of the pharmaceutical industry by developing policy, strengthening recommendations, facilitating to internationalization of the industry, and boosting public relations.

→ jpma.or.jp

