LIFE SCIENCES INDUSTRY REPORT 2025

PART 4: DIGITAL HEALTH

Uncover the transformative trends that will drive the life sciences industry ahead, backed by expert commentary and data-driven insights.

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Editors’ introduction

One of the most remarkable shifts in modern healthcare is how seamlessly digital platforms are becoming part of the drug development journey. Think advanced data analytics, wearable health devices, and AI-driven models – all working together to shorten the path from the lab bench to the patient’s bedside. These technologies are helping to personalise treatments, anticipate patient responses, and streamline clinical trials, reshaping how new medicines come to life.

The agility of software development stands in stark contrast to traditional pharmaceutical development cycles. While bringing a new drug to market typically involves years of clinical trials and substantial investment, software solutions can be refined and updated swiftly, even within regulated environments. This flexibility allows healthcare providers to respond more dynamically to patient needs and emerging challenges.

Recent regulatory frameworks, particularly the FDA’s Prescription Drug Use-Related Software guidance, signal a maturing ecosystem that recognises software’s unique position in healthcare delivery. This framework demonstrates how regulatory bodies are adapting to support innovation while maintaining their commitment to patient safety and evidence-based approaches.

But progress isn’t without its hurdles. We still face big questions about data privacy, hardware suitability, and making sure that digital health solutions are accessible to all. Balancing the rapid pace of innovation with patient safety and ethical standards isn’t easy, but it’s essential.

As we look ahead, the convergence of software, technology, and healthcare promises to deliver increasingly personalised and responsive treatment options. But, while the emergence of software in treatment is an exciting prospect, elsewhere in digital health, companies have been carefully creating and refining their digital health portfolios, most notably in the biopharma space. With new players entering the field, will the early adopters of digital health technologies be able to maintain their competitive edge? The last 12 months have certainly left us with plenty of questions to be answered in 2025.

In this edition of the Life Sciences Industry Report, we explore these developments and their implications for our industry. While the challenges ahead are significant, the potential to improve patient outcomes through digital innovation has never been greater.

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Deep Dive Editor

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Digital health

New entrants

Since 2023, Pfizer, Sanofi, and BMS have entered the top 10 Strategic Fit list, each expanding their digital health portfolios by over 22% since early 2022.

AstraZeneca's leadership

AstraZeneca has maintained its leading position from 2023, having announced 40 digital health partnerships over the past three years.

Top innovator

Gilead Sciences claims the top position on the Pharmaceutical - Digital Health Innovation Index 2024, climbing from its #2 ranking in 2023.

Best-performing ventures

Gilead Sciences leads in best-performing ventures for research, while Otsuka Pharmaceuticals tops the list for ventures focused on patient engagement.

Strategic expansion

The digital health portfolios of major pharmaceutical companies are rapidly expanding, reflecting a significant strategic shift towards digital health innovation.

Data and insights powered by Galen Growth

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Pharmaceutical Digital Health Innovation Index, 2024 Edition

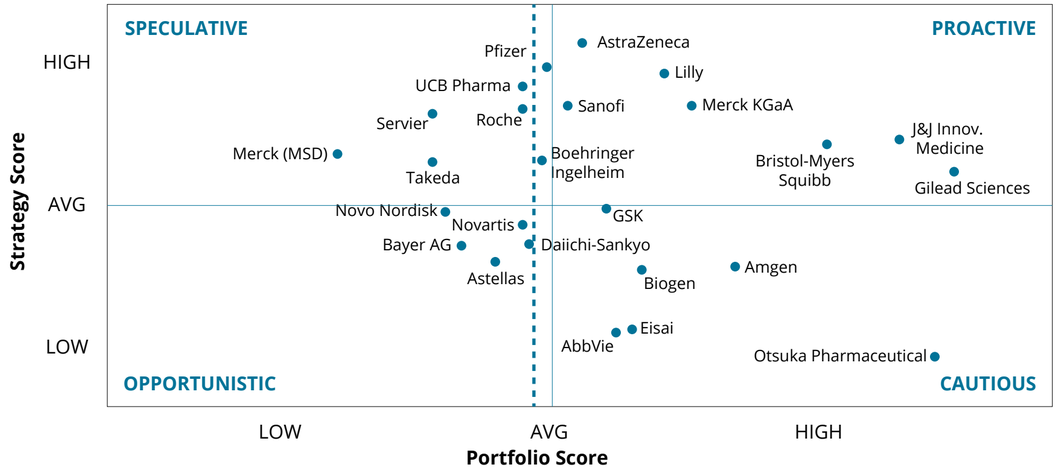
Digital health remains a transformative force in today's rapidly evolving healthcare landscape, continuously reshaping healthcare delivery, management, and patient experiences.

Galen Growth's Pharmaceutical Digital Health Innovation Index 2024

Digital health remains a transformative force in today's rapidly evolving healthcare landscape, continuously reshaping healthcare delivery, management, and patient experiences.

Biopharma companies, recognising the potential to improve outcomes and streamline drug development, are carefully crafting and reshaping their digital health portfolios. This year, pharma has shifted attention to two key areas: internal R&D processes enhanced by AI technology and customer-focused innovations, such as direct-to-consumer platforms. This report examines the portfolios of the most active biopharma companies worldwide, offering an in-depth analysis of their strategic priorities, partnerships, and impact on healthcare's future. A summary of the findings are here, and the full report can be downloaded from Galen Growth.

For this year's analysis, **there was no change in** the top 25 companies. It is becoming evident that early adopters of digital healthcare technologies in biopharma, who once held a competitive edge, may now be losing ground to more focused competitors who have adapted based on industry learnings. These fast followers have achieved greater agility by leveraging refined strategies and advances in data integration and AI. At the same time, some early movers struggle with shifting priorities and fragmented initiatives, highlighting the need for continuous evolution in a rapidly changing landscape.



Strong venture portfolios should be aligned with biopharma's corporate pain points and strategy to avoid digital health theatrics.

Pharmaceutical Digital Health Innovation Index 2024: Top Strategic Fit ranking

Strategic Fit ranking		
2024 Ranking	Companies	2023 Ranking
1	AstraZeneca	#1 ▸
2	Pfizer	#11 ▲
3	Lilly	#4 ▲
4	UCB Pharma	#3 ▼
5	Merck KGaA	#5 ▸
6	Sanofi	#16 ▲
7	Roche	#2 ▼
8	Servier	#9 ▲
9	J&J Innovative Medicine	#6 ▼
10	Bristol-Myers Squibb	#22 ▲

Top performers in the **Strategic Fit** analysis have expanded their portfolios globally and are focusing their partnerships to accelerate drug development. Additionally, there is a strong alignment between the biopharma companies' target therapeutic areas and the ventures' focus areas, essential for addressing patient and franchise needs.

The Strategic Fit must be balanced by ensuring the portfolio is sufficiently mature and ready for market. This way, the company can ensure its digital health strategy is effective and efficient rather than distracting from critical business tasks.

AstraZeneca has maintained its leading position from 2023, having announced 40 digital health partnerships over the past three years, with 78% of the new partners developing solutions that leverage AI. New entrants to the top 10 Strategic Fit list since 2023 include Pfizer, Sanofi, and BMS, each expanding their digital health portfolios by over 22% since early 2022.

Pharmaceutical Digital Health Innovation Index 2024: Top Venture Portfolio Score ranking

Portfolio Score ranking		
2024 Ranking	Companies	2023 Ranking
1	Gilead Sciences	#2 ▲
2	Otsuka Pharmaceutical	#1 ▼
3	J&J Innovative Medicine (Janssen)	#4 ▲
4	Bristol-Myers Squibb	#3 ▼
5	Amgen	#7 ▲
6	Merck KGaA	#6 ▸
7	Lilly	#5 ▼
8	Biogen	#9 ▲
9	Eisai	#11 ▲
10	GSK	#10 ▸

Selecting the right ventures is crucial for successful partnerships and impacts the speed at which solutions reach the market. Collaborating with established ventures led by experienced teams enhances the chances of faster product delivery with reduced development effort. On the other hand, partnerships with less mature ventures, while potentially groundbreaking, involve higher risks. These ventures often require greater support from the biopharma partner, and the timeline for realising returns may be extended. Recognising the growing importance of technology and data, biopharma companies increasingly partner with ventures that harness artificial intelligence, driving broader adoption of AI-driven solutions.

Nevertheless, strong venture portfolios should be aligned with biopharma's corporate pain points and strategy to avoid digital health theatrics, where the partnership has little added value to the patient or business beyond PR.

Gilead Sciences claims the top position this year, climbing from its #2 ranking in 2023. Within the top 25 biopharma companies, Otsuka leads with the highest proportion of ventures leveraging AI and top Patient Care portfolio.

Value chain focus on R&D and patient engagement within the biopharma portfolio

Top Patient Care Portfolio	Top Patient Care Portfolio
Otsuka Pharmaceutical	Otsuka Pharmaceutical
Eisai	Eisai
Gilead Sciences	Gilead Sciences
J&J Innovative Medicine	J&J Innovative Medicine
Biogen	Biogen
Novartis	Novartis
Boehringer Ingelheim	Boehringer Ingelheim
Lilly	Lilly
GSK	GSK
Novo Nordisk	Novo Nordisk

To better understand the venture portfolios, it is helpful to consider the strength of each based on key strategic business areas: research & development and patient engagement..

The Portfolio Strength for each biopharma was evaluated separately for ventures in the portfolio that had solutions in the Research Solutions and Clinical Trials clusters or patient engagement tools (Patient Solutions cluster or Diagnosis value propositions)*.

This perspective shows that Gilead Sciences and Biogen are in the top 5 names on each list. **Gilead Sciences takes the top spot for the best-performing ventures for research, and Otsuka Pharmaceuticals tops the best-performance list for ventures with a focus on patient engagement.**

Digital Health Innovation Index - Pharmaceutical

The Digital Health Innovation Index for biopharma measures how effectively companies have integrated digital healthcare technology into their business models and the degree to which strong ventures have been selected for partnership development. It places particular emphasis on partnerships formed over the past three years. It considers the growing focus of biopharma companies on enhancing efficiency and supporting biopharma research using digital health tools. All data for the analysis is from HealthTech Alpha, a Galen Growth solution.

Has the company made digital health a strategic priority across the global organization? Has the biopharma company:

- Distributed partnerships globally
- Integrated digital health into the strategic therapeutic areas
- Adopted the use of artificial intelligence
- Integrated digital health tools in drug development
- Maintained a focus on building a digital health portfolio through strategic partnering
- Strategic Fit
- Portfolio Strength

Does the portfolio include digital health ventures that will contribute to the success of the partnerships and the speed to market of the solution? Do they have:

- A strong management team
- Evidence of scientific or medical benefit
- Use of artificial intelligence technology
- Financial strength
- Proven digital health maturity[1]

SCOPE: The analysis considers ventures in the six global regions for digital health: Asia Pacific, the Middle East, Western Europe, North America, South America (key ecosystems), and Africa.

SOURCE: Analysis and data by Galen Growth Research, powered by HealthTech Alpha

1) HealthTech Alpha's proprietary analytics, including the Maturity Score and Evidence Signal are defined on page 38

About Galen Growth

About the author

Sara Schmachtenberg is the Head of Data and Analytics at Galen Growth, bringing over a decade of experience in the medical device industry across corporate and startup environments. Schmachtenberg's passion for data-driven decision-making has been pivotal in addressing the challenges of digital health innovation. Galen Growth is the leading provider of business intelligence, specialising in digital technology innovation in healthcare. With approximately a decade of unparalleled expertise, Galen Growth has consistently delivered cutting-edge research, analytics, and insights to industry leaders and investors, solidifying its reputation as the premier authority in this dynamic field.

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Understanding PDURS: A new era for digital health and pharma

The FDA's Prescription Drug Use-Related Software (PDURS) framework marks a significant milestone for healthcare in the US. Introduced to facilitate the integration of software with prescription drugs, this framework is set to transform how pharma manufacturers enhance the clinical value of their products.

During a recent webinar, Jonah Comstock, editor-in-chief at pharmaphorum, sought to demystify the new process through an insightful conversation with industry experts Marty Culjat, SVP and global head of digital medicine and regulatory innovation at EVERSANA, and Edward Cox, head and general manager of digital health and medicines at Pfizer.

The PDURS framework: an overview

A potential workaround to existing restrictions such as anti-kickback laws and rigorous drug-device combination approvals, the PDURS framework allows pharmaceutical manufacturers to add software to a drug label, provided it demonstrates clinical benefit.

"Up until now, the way to pair software with a drug was through companion apps or a drug-device combination," noted Culjat. This new PDURS framework, however, enables more flexibility and direct clinical claims about the software's benefits.

There are two primary categories within the PDURS framework, including promotional software, which does not claim clinical benefits, and required labelling, which does, Culjat explained. The latter is particularly innovative, as it allows the software to be included on drug labels, emphasising its clinical advantages. "It's a flexible approach and definitely allows you to position the product as it's intended to be," he said.

The PDURS framework, presented in 2018 and refined through public comments and draft guidance, aims to bridge the gap between digital solutions and pharmaceuticals. By allowing software that provides a clinical benefit to be included on drug labels, PDURS opens the door to a range of new possibilities for enhancing patient care and improving treatment outcomes.

Clinical and Commercial Implications

According to the speakers, one of the main attractions of the PDURS framework is its potential to address various clinical and commercial challenges faced by pharmaceutical companies. Culjat highlighted several possible use cases for PDURS, including personalised dosing, side effect management, behavioural support, and prognostics. These applications can significantly enhance the clinical value of drugs, making them more effective and safer for patients.

In addition, they underscored the potential commercial advantages including providing brand differentiation in competitive markets, maintaining treatment duration, justifying value compared to generics, and retaining brand demand longer during the lifecycle as possible positive benefits PDURS may provide.

Cox stated, “In my view, this is one of the most exciting steps that’s happened at the intersection of digital and pharma in a decade.”

From a commercial perspective, PDURS offers a way for branded drugs to stand out in a crowded market, particularly as they approach the loss of exclusivity.

The PDURS framework also addresses several regulatory hurdles that have traditionally impeded the integration of digital solutions with pharmaceuticals. Offering a more streamlined approval pathway reduces the time and cost associated with bringing these innovative products to market. This factor is significant for solutions that address critical issues such as personalised dosing and side effect management, where timely implementation can significantly impact patient outcomes.

“In my view, this is one of the most exciting steps that’s happened at the intersection of digital and pharma in a decade,”

- Edward Cox.

Preparing for the Future: Strategic Considerations

As the PDURS framework becomes more established, both software developers and pharmaceutical companies must strategise to maximise its potential. To help organisations navigate this new terrain, Culjat provided advice for stakeholders on both sides. For software developers, he recommended identifying unmet needs within the pharma pipeline and tailoring solutions to address these gaps. “The first thing to do would be to understand where your solution can provide value,” he explained. “You don’t want to come at this with a solution in search of a problem,” he emphasised.

Engaging with the FDA early on can also be beneficial. “It would be valuable to have that initial first level of validation on your approach with the FDA, to be able to hand that over to your partners and your discussions with pharma,” Culjat advised. “The earlier you can go to the FDA and then have those discussions, the better off you would be to be able to move this forward without a lot of questions from legal and regulatory within the pharma organisation.”

For pharmaceutical companies, the key lies in integrating PDURS into their broader digital health strategies. This involves not only identifying the most promising use cases but also securing internal buy-in from various stakeholders. “It’s a matter of building the case, getting the brand team’s engagement and interest, and then really finding the champions internally,” Culjat said.

Cox highlighted the importance of bespoke solutions tailored to specific pharmaceutical assets. “These are world-class assets that deserve really crafted experiences,” he stated. He noted that while a basic, off-the-shelf model might be less appealing, a tailored approach could significantly enhance the clinical and commercial value of the drug.

“These are world-class assets that deserve really crafted experiences,”

- Marty Culjat.

Additionally, the PDURS framework encourages collaboration between software developers and pharmaceutical companies. By fostering partnerships and leveraging the expertise of both parties, the framework can drive innovation and bring cutting-edge solutions to market more efficiently. This collaborative approach not only benefits the companies involved but also has the potential to improve patient outcomes on a broader scale.

The potential impact of the PDURS framework extends beyond immediate clinical and commercial benefits. By establishing a clear regulatory pathway for the integration of digital solutions with pharmaceuticals, it sets the stage for ongoing innovation in the healthcare sector. As more companies embrace this framework and develop new applications, the possibilities for enhancing patient care and treatment outcomes will continue to expand.

In closing, speakers emphasised that the PDURS framework represents a significant opportunity for innovation at the intersection of digital health and pharmaceuticals. By enabling the

integration of clinically beneficial software with prescription drugs, it promises to enhance patient outcomes, streamline regulatory processes, and offer substantial commercial advantages. As the healthcare industry continues to evolve, stakeholders who embrace this new framework will be well-positioned to lead the way in digital health innovation.

Cox concluded "For nearly the first 20 years of digital health, it was hard to explain very explicitly or very clearly the benefit a digital solution could deliver.

... We had to try to navigate our way through the fog before, but if the language becomes final in the way that we all hope, that it will create a brand new clarity, and that I think it's going to make a profound difference."

Click here to view "PDURS explained: The FDA's new framework for adding software to drug labels" on-demand.

About EVERSANA

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