

Chapter 17 / Capítulo 17

Primum non nocere: Software engineering
for medicine
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Chapter 17. Business Models in Digital Health

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“No matter how brilliant an innovation may be, no matter how rigorous its validation *is, no matter how ethical its design is*, if there is no sustainable business model to fund it, it will never reach the patients who need it. Digital health is not just science and technology; it is also economics, and those who ignore this reality are doomed to see their ideas die in the laboratory.”

Medical software developers tend to believe that technical quality and clinical evidence are sufficient to guarantee success. They develop a brilliant algorithm, rigorously validate it, publish excellent results, and expect the world to recognize it. However, the world does not work that way. Between an excellent product and its widespread adoption lies a chasm that can only be bridged with a solid business model. Who is going to pay for this? How much are they willing to pay? How is payment structured? What incentives do buyers have? These questions, which many developers view as mundane, are actually what determines whether an innovation makes it into practice or remains on paper.

The business model is not an afterthought to development; it should be part of the design from the very beginning. It determines which features are viable, what level of evidence is needed, which marketing channels are used, and which partnerships are established. A well-developed business model can compensate for technical weaknesses; a poorly developed business model can sink even the best product. That is why it is essential for development teams to include, from the very beginning, people with knowledge of the healthcare market, financing, regulation, and competition.

In this chapter, we explore the different business models in digital health, their advantages, and their limitations. We begin with the fundamental question: who pays. We analyze the three major payers: public systems, private insurers, and the patients themselves. We will continue with digital therapeutics (DTx) and reimbursement pathways, emerging fields with great promise and complexity. We address digital prescribing, which turns software into a product that doctors can prescribe like a drug. Finally, we discuss sustainability and technology transfer, the long-term challenges that determine whether a project survives beyond initial funding.

17.1 WHO PAYS: PUBLIC SYSTEMS, INSURANCE, PATIENTS

“No algorithm is so brilliant that it can survive a poorly chosen payment model; technology heals, but money distributes it.”

The question “who pays?” seems, in its formulation, almost naively simple. However, this apparent simplicity conceals a strategic complexity that determines, with the force of commercial destiny, everything else: the price that can be set, the type and volume of evidence that must be generated, the distribution channels that will be viable, the communication strategy that will resonate, and the institutional partnerships that will be necessary. A product designed to be purchased directly by patient-consumers has absolutely nothing in common in its business architecture, with one designed to be financed by a public health system. Confusing these markets, ignoring their distinct logics, or attempting to construct a hybrid model without understanding the tensions between its components is one of the surest paths to commercial failure, no matter how sophisticated the underlying technology may be.

17.1.1 THE HEALTHCARE LEVIATHAN: SELLING TO THE PUBLIC SYSTEM

Public health systems, funded predominantly through taxation and responsible for universal coverage of entire populations, are the dominant payers in Europe, Canada, Australia, and a growing number of countries in Latin America and Asia. Their decision-making logic is not that of the consumer market but rather the maximization of population health subject to rigid budgetary constraints. They are not attracted primarily by technological innovation for its own sake or by abstract algorithmic sophistication; they are interested exclusively in the added health value that the product can generate relative to its cost compared with available alternatives. Software that costs the same as standard practice but does not significantly improve outcomes will not be adopted; software that costs substantially more will be funded only if the additional clinical benefit, rigorously demonstrated, justifies the incremental expenditure from a public health perspective.

The commercial process for public systems is a marathon rather than a sprint. It typically involves a formal evaluation by a health technology assessment agency that will analyze the

evidence of efficacy, safety, and cost-effectiveness; a price negotiation that can last for months and in which the manufacturer must demonstrate flexibility; and eventually to inclusion in the catalog of covered services, which enables access for the population. From the initial submission to actual availability for patients, two to five years may elapse, during which the manufacturer must keep the product up to date, generate additional evidence if requested by evaluators, and manage complex relationships with multiple stakeholders. It is a process that is costly in terms of financial and human resources, but the potential reward is enormous: once included in public coverage, the product gains access to populations of millions of patients with predictable and stable revenue streams for years, often with protection against competitors through contractual exclusivity or regulatory barriers to entry.

Public systems have developed increasingly sophisticated purchasing mechanisms that developers must understand and navigate. Risk-sharing agreements, where the final price paid depends on the actual health outcomes achieved in the treated population, align the manufacturer's incentives with those of the system and reduce the adoption risk for the payer, but they require an outcome monitoring infrastructure that many hospitals do not yet have. Early access agreements allow for product promotion while additional evidence is gathered, with price reviews once more robust data become available. Staggered payments, where the cost is spread over time in alignment with implementation, facilitate short-term budget viability. Each of these models requires careful contractual design and the ability to demonstrate value on an ongoing basis.

17.1.2 MARKET LOGIC: NEGOTIATING WITH PRIVATE INSURERS

Private health insurers, which dominate the U.S. system but are also present as complements or alternatives in almost every country, operate under a radically different logic that combines concerns about clinical value with commercial imperatives of competitiveness. Their goal is not only to maximize the health of the covered population but also to offer an attractive insurance product that retains existing customers and captures new ones while maintaining corporate profit margins. This calculation introduces variables that public systems ignore: perceived satisfaction among policyholders, differentiation from competitors, brand value associated with technological innovation, and the impact on costs over shorter time horizons than those used in public HTA evaluations.

An insurer may be genuinely interested in funding software that substantially improves the patient experience—by streamlining appointments, reducing wait times, and facilitating smooth communication—even if evidence of direct cost savings is limited because retaining satisfied customers has a quantifiable commercial value. It may prioritize interventions that reduce hospital admissions in the medium term, even if the initial investment is high, because its business model makes it particularly sensitive to the use of costly services. It may seek technologies that attract corporate employers who purchase insurance for their employees, a particularly lucrative market segment. The calculation is more complex, less publicly transparent, and highly variable among insurers with different positioning strategies.

The process of selling to insurers is fragmented and relationship-driven. There is no central agency that evaluates and determines the entire market; each entity makes independent decisions on the basis of its internal medical committees, its actuarial analyses, and its commercial negotiations. This means that the manufacturer must build commercial relationships with each relevant insurer, tailor the value proposition to their specific priorities—one may prioritize cost reduction, another product differentiation, and another customer satisfaction for those with chronic conditions—and maintain regional sales teams covering specific geographies. The market is more fragmented than the public sector but also more dynamic: an insurer can become a strategic partner that accelerates mass adoption if it includes the product in its standard catalog, generating significant revenue before public processes have even begun.

17.1.3 THE PATIENT AS A CUSTOMER: THE DIRECT-TO-CONSUMER MODEL

The third revenue stream involves the patient themselves, who purchases the product directly out-of-pocket. This model is dominant in wellness, preventive health, digital fitness, and lifestyle monitoring applications, but it also operates in specific clinical areas, such as mental health (cognitive-behavioral therapy apps), diabetes management (over-the-counter continuous

glucose monitoring), and home-based cardiac rehabilitation programs. The fundamental advantage of this model is its apparent simplicity: there are no institutional intermediaries to convince, no formal evaluation processes to go through, only the direct market where the product must compete for the consumer's attention and money.

However, this simplicity is deceptive. The price must be affordable for individuals paying with limited personal resources, which drastically compresses margins and limits the ability to recoup large investments in development and clinical validation. Adoption depends entirely on marketing, visibility in app stores, user reviews, and word of mouth rather than on recommendations from healthcare professionals that confer medical legitimacy. The model raises acute ethical issues of equity: only patients with available financial resources can access it, potentially widening the health inequalities that technology is supposed to reduce.

The direct-to-consumer payment model is sustainable for products with low development costs, high digital scalability, and massive potential user volume. It is difficult to sustain complex products that require rigorous clinical evidence, costly regulatory validation, and sophisticated maintenance. For this reason, many products that start with the direct-to-consumer model eventually seek to transition to public or insurance funding to expand their reach and stabilize their revenue or adopt hybrid models where basic functionality is free and access to advanced features requires a subscription.

17.1.4 HYBRID MODELS AND THE ARCHITECTURE OF STRATEGIC CHOICE

There are hybrid configurations where payments are distributed among multiple actors, creating funding ecosystems that are more resilient but also more complex to manage. A public system may fund the base cost of medical software while the patient pays a copay for premium features. An insurer may offer the product at no direct cost to its policyholders as part of their benefits package, having negotiated a corporate price with the manufacturer. An employer may pay for a digital wellness program for its workforce as part of its strategy to reduce insurance costs and absenteeism. These hybrid models may be more viable than relying on a single payer, but they require sophisticated contractual architecture and a clear allocation of responsibilities among the parties.

For medical software developers, choosing the right payment model is not a tactical decision that can be postponed until the product is finished; it is a fundamental strategic determination that must inform the design from the outset. A product for a rare disease, with small target populations and a need for rigorous evidence, should likely target exclusively public systems that can finance the high cost per patient through the logic of healthcare value. A general wellness product, with the potential for massive viral reach and low marginal costs, can thrive in the direct-to-consumer model. A product for a common chronic disease—such as diabetes or hypertension—may have viable options in multiple markets and require careful analysis of competition, the ability to generate evidence, and available commercial resources to determine the optimal strategy. The critical point is that this decision should not be left until the end but rather should guide the product architecture, the design of evidence studies, and the building of organizational capabilities from day one.

For clinicians operating in these ecosystems, understanding payment models allows them to be realistic about what they can expect from the technology and how to advise their patients. A product available only through out-of-pocket payment raises ethical dilemmas of unequal access that must be acknowledged. A product dependent on public funding may take years to reach everyday practice. A product subject to changing insurer policies may disappear from coverage without warning. This understanding allows physicians to participate informedly in debates on coverage and prioritization policies and to advise individual patients on their actual options.

Value-based payment agreements, where the price is dynamically adjusted on the basis of achieved health outcomes, become more widespread as monitoring infrastructure improves. Institutional subscription models, where hospitals pay annual fees for access to product catalogs, will gain ground as a mechanism for technology portfolio management. Freemium models, with free basic features funded by advertising or data and paid advanced features, will be used for patient-facing products. Innovation in business models will be as critical to success as technological innovation itself.

Behind every payment model are real patients who hope to benefit from the technology. An excellent product that cannot find a viable business model is, from a public health perspective, a product that does not exist. However, a business model that works commercially yet is ethically

unacceptable—because it exploits sensitive data and because it widens inequalities in access because it shifts costs onto the most vulnerable—is equally unacceptable. True success is not just about finding who pays, but doing so in a way that ensures that the technology reaches everyone who can benefit from it—fairly, sustainably, and in a manner worthy of the trust patients place in us.

17.2 DIGITAL THERAPIES (DTX) AND REIMBURSEMENT PATHWAYS

Over the past decade, a category of health products has emerged that challenges traditional classifications and redefines the boundaries between software and medical therapy. Digital therapeutics, known internationally as DTx (digital therapeutics), represent a qualitative evolution from conventional health apps: they are interventions based on rigorous scientific evidence, explicitly regulated as medical devices by agencies such as the FDA or the EMA, that prevent, manage, or treat specific medical conditions exclusively through software.⁽¹⁾ Unlike general wellness apps that promise vague lifestyle improvements, DTx must demonstrate clinical efficacy comparable to that of drugs, obtain regulatory approval under the same safety and efficacy standards, and be prescribed by physicians as integral components of formal therapeutic plans. Their arrival in the healthcare ecosystem presents transformative opportunities for access to care but also presents complex challenges in terms of methodological development, regulatory validation, and, perhaps most critically, establishing sustainable reimbursement pathways that enable access for patients who need them.

The line between a conventional health app and legitimate digital therapy is not always visible to the casual consumer, but there are clear distinguishing criteria that professionals must understand. A genuine DTx must have a specific and explicit therapeutic purpose on the basis of a reasonably well-characterized biological or psychological mechanism of action. Efficacy must be demonstrated in clinical studies that meet the methodological standards required for drugs: randomized controlled trials where ethically feasible, clinically relevant and validated outcome measures, subgroup analyses, and adequate safety monitoring. It must be formally regulated as a medical device, with the corresponding quality certification and traceability. It must be explicitly designed for use under medical supervision and integrated into broader therapeutic plans rather than functioning as a standalone self-care intervention. These criteria radically distinguish DTx from mass-market wellness apps, which require neither clinical evidence nor professional supervision for commercialization.

17.2.1 DEVELOPMENT AS A SCIENCE: CLOSER TO A DRUG THAN TO AN APP

The development of digital therapy is, in its fundamental architecture, more similar to the development of a drug than to that of a conventional commercial app. It requires explicit conceptualization of the therapeutic mechanism of action: how does the software produce its clinical effect? By educating the patient about their condition? By systematically modifying risk behaviors through digitally implemented cognitive-behavioral psychology techniques? By continuously monitoring physiological parameters with real-time feedback that allows for therapeutic adjustments? By activating neuroplastic processes through digital neurorehabilitation interventions? This understanding of the mechanism is not merely an academic option; it is necessary to design appropriate clinical studies, to convince skeptical regulatory agencies, and to differentiate commercially from the competition of unvalidated applications.

The cost of bringing a DTx to the regulated market is typically estimated at between two and ten million euros, depending on the complexity of the intervention, the number of indications sought, and the specific requirements of regulators in the target jurisdictions. This investment includes the technical development of software to meet the required medical quality standards, the conduct of clinical trials that can last for years, the preparation and submission of comprehensive regulatory dossiers, and initial market access activities. It is a considerable investment, but one that is manageable for many health technology companies, especially compared to the more than one billion dollars typically required to develop a new molecular entity drug. This more favorable cost ratio, combined with shorter development cycles and the ability to update products postmarket, makes DTx a particularly attractive therapeutic innovation opportunity for investors and entrepreneurs.

17.2.2 THE BIG CHALLENGE: WHO PAYS AND WHY

The central challenge in determining the commercial success or failure of digital therapy is not its technical or clinical development but rather the establishment of sustainable reimbursement mechanisms. Who pays for these interventions? How is their price determined in the absence of clear reference markets? What additional evidence, beyond regulatory approval, do payers need to include them in their covered benefits catalogs? These questions lack universal answers and vary dramatically across healthcare systems, creating a fragmented reimbursement landscape that developers must navigate strategically.

In Germany, the digital health applications (DiGA) procedure began in place in 2019, a pioneering regulatory and reimbursement framework that has enabled dozens of DTx to be funded by the public health system.⁽²⁾ The German model allows apps that meet basic safety, functionality, and quality requirements to be provisionally included in the benefits catalog, with a price initially set by the manufacturer for the first year. During this temporary inclusion period, the manufacturer must complete a clinical study demonstrating the specific benefits of the app for the German population. If the study confirms the therapeutic value, the inclusion becomes permanent, and the price is negotiated with the health insurance associations. If the study is negative or not completed, the app is removed from the catalog. This hybrid model lowers the initial barrier to entry, allowing early access for patients while ensuring that only apps with solid evidence of real benefit remain funded in the long term.

The German model has proven to be a significant operational success, with dozens of approved applications covering indications ranging from type 2 diabetes to major depression, benefiting millions of patients with guaranteed access at no direct cost. It has been empirically demonstrated that it is technically and politically possible to systematically integrate therapeutic software into the benefits portfolio of a public health system, using transparent criteria and agile processes that do not sacrifice scientific rigor. Other European countries, including France, Belgium, and the Netherlands, are developing similar processes inspired by the German experience, suggesting that this model will likely expand in the coming years. For DTx developers, a deep understanding of the German framework is strategically essential, as it sets precedents that influence the evolution of reimbursement across multiple markets.

In the United States, the reimbursement landscape is more fragmented and evolving. Some large-scale private insurers have begun to selectively cover certain DTx, particularly in areas such as mental health and diabetes, where cost-effectiveness evidence is more robust. Medicare, the federal program for older adults, is actively exploring pathways for including digital therapies, but the process is complex and slow.⁽³⁾ The FDA has established accelerated approval pathways for DTx, but regulatory approval does not guarantee reimbursement in the U.S. system, where each payer makes independent decisions. This fragmentation creates opportunities for creative negotiations with innovative insurers but also significant operational complexity.

17.2.3 VALUE, PRICE, AND THE ECONOMICS OF DIGITAL THERAPEUTICS

For a payer—whether a public system or a private insurer—to agree to fund digital therapy, the manufacturer must build a compelling case for value that justifies the requested price. This value can manifest in clinical, economic, or human dimensions, and typically, the most robust combination integrates all three dimensions. Clinical value is demonstrated through measurable improvements in health outcomes, such as a reduction in symptoms, improvement in biological markers, prevention of complications, or increased remission of chronic diseases. Economic value is quantified through savings in healthcare costs: reduced hospital admissions, fewer emergency room visits, optimized use of medications, or prevention of costly procedures. Human value, which is more difficult to monetize but equally important, includes improvements in quality of life, reduced treatment burden, greater patient autonomy, and satisfaction with the care received.

Pricing DTx is inherently complex because it lacks established reference markets comparable to those for generic pharmaceuticals. The price must reflect demonstrated value but also recoup development costs, consider the prices of existing or developing competitor products, and respect the willingness to pay of institutional buyers. In the German model, the manufacturer freely sets the price during the provisional inclusion year but then faces negotiations with powerful collective buyers. In other markets, the price may be determined through direct negotiation from the outset or through competitive bidding processes. In all the cases, a pricing strategy grounded in rigorous value analysis, with clear sensitivity scenarios and reserve points, is indispensable for

commercial negotiations.

17.2.4 MARKET STRATEGY AND THE ROLE OF THE CLINICIAN

For developers, entering the digital therapeutics market requires a specific strategy that goes beyond the mere creation of good software. Clinical studies must be designed from the product's conception, in collaboration with methodological experts in clinical research, ensuring that endpoints will be recognized as relevant by regulators and payers. Regulatory dossiers must be prepared with the same rigor as would be applied to a new drug, documenting not only efficacy but also safety, software quality, and traceability of the development process. It is necessary to understand the reimbursement processes specific to each target country and adapt the evidence and commercialization strategy to them. It is necessary to develop strategic relationships with payers, relevant scientific societies, and patient associations that can influence coverage decisions.

For clinicians, DTx represents a new therapeutic class that they must become familiar with, critically evaluate, and learn to integrate into their practice. Just as previous generations of physicians had to learn to prescribe antibiotics, antihypertensives, or antidepressants when these emerged, the current generation must develop competence in “digital prescribing.” This requires specific training on which DTx are available for which indications, what evidence supports them, how to monitor the patient's response, and when to adjust or discontinue the intervention. However, it also requires a shift in mindset regarding the therapeutic relationship: a DTx is not a passive drug that the patient consumes; it is an active intervention that requires the patient's involvement in their own care. The role of the physician is evolving toward that of motivator, monitor, and supporter rather than a mere prescriber.

We are likely to see rapid expansion in areas where the evidence is more mature: mental health (depression, anxiety, insomnia), diabetes mellitus, cardiovascular diseases, and neurological rehabilitation. Hybrid models are likely to emerge that combine DTx with medications—for example, apps that optimize medication adherence—or with wearable devices that provide input data for therapeutic algorithms. Artificial intelligence is likely to enable increasingly personalized digital interventions, tailoring content and frequency to each patient's individual characteristics and responses, thereby increasing efficacy. However, there are also significant risks: the proliferation of DTx of varying quality that confuses the market; the lack of long-term evidence for many applications; the slowness of reimbursement processes in many markets; and potential resistance from clinicians who perceive DTx as threats to their autonomy or as an outsourcing of responsibility.

DTx solutions are not an end in themselves but rather a means to tangibly improve the lives of people living with chronic conditions. Behind every approved app are real patients who can benefit from better diabetes management, reduced symptoms of depression, and a higher quality of life during rehabilitation. The ultimate goal is not to create a profitable business—although financial sustainability is a necessary condition—but to help these patients live better lives. If developers keep this human purpose at the center of their decisions regarding design, evidence, pricing, and reimbursement, their strategies will be more coherent, more ethical, and more resilient. In the end, what justifies the existence of digital therapies is not the sophistication of the code but the genuine therapeutic value they provide to those who need it most.

17.3 THE PRESCRIPTION OF THE FUTURE: HOW DOCTORS PRESCRIBE BITS AND BYTES

“Prescribing an app is not *technophilia*; it is recognizing that healing can come in the form of code when that code is validated, regulated, and prescribed with the same responsibility as any molecule.”

The idea that a doctor could prescribe an app as if it were a drug contains something of a technological revolution and, simultaneously, something deeply natural in therapeutic logic. After all, if software can demonstrate measurable physiological or psychological effects, if it can reduce symptoms, modify risky behaviors, or prevent medical complications with the same robustness as a pharmacological intervention, why should it not occupy a legitimate place in the clinician's therapeutic arsenal? Digital prescribing is precisely this: the formal act by which a healthcare professional recommends, indicates, or explicitly prescribes a digital therapy as an integral component of a specific patient's treatment plan. However, behind this apparent

conceptual simplicity lies a profound transformation of clinical practice, with implications ranging from operational logistics to the very nature of the therapeutic relationship between doctor and patient.

Digital prescribing cannot be reduced to the casual conversation in the office where the doctor suggests, “Download this app; it might help you.” It is a structured, documented, and technically integrated process that must fit seamlessly into the existing clinical workflow, or doctors simply will not adopt it. This process typically involves five sequential steps that transform a casual recommendation into a formal medical intervention.

17.3.1 THE FIVE STEPS OF THE DIGITAL THERAPEUTIC CHAIN

The first step is clinical diagnosis and determination of indications. The physician evaluates the patient and determines, on the basis of their specific medical condition, individual characteristics, comorbidities, preferences, and capabilities, whether they might benefit from a particular digital therapy. This selection does not differ in principle from the prescription of medication: not all antidepressants are suitable for all patients with depression, and not all digital therapies are suitable for all potential candidates. Physicians must be familiar with the available options, their efficacy profiles in subgroups, their relative contraindications, and their patient engagement requirements. Inappropriate selection—prescribing a digital therapy that is in, that the patient is unable to use, or that is not indicated for their specific profile—is just as problematic as inappropriate drug prescribing.

The second step is generating the formal prescription. In the most advanced systems, this involves creating a structured “digital prescription” that the patient can redeem on an authorized platform or specialized app store. This digital prescription includes crucial metadata: the specific therapy prescribed, the indicated duration of treatment, the agreed-upon therapeutic goals, personalized instructions for use, and follow-up criteria. In many cases, the prescription is linked to a unique activation code that unlocks the full therapeutic version of the app, while the publicly downloadable version may be limited in functionality or require direct payment. This activation code mechanism is what allows the healthcare system or insurer to cover the cost, while the patient gains access without immediate financial burden.

The third step is actual dispensing. The patient receives the prescription, typically via text message, email, or notification on a personal health portal, and accesses the digital therapy through the designated platform. The system verifies in real time that the prescription is valid, that it has not been redeemed previously, that the patient is eligible for funded access and that the therapeutic version is appropriate for their condition. In some models, payment is processed at this stage via or through direct billing to the healthcare system; in others, the patient pays and then requests reimbursement; in more advanced models, the cost is completely invisible to the patient and absorbed by institutional funding.

The fourth step is therapeutic use by the patient. Over weeks or months, the patient interacts with the app according to the prescribed protocol: completing intervention modules, recording symptoms or behaviors, receiving feedback, and potentially participating in interactions with human therapists coordinated through the platform. The app collects data on adherence (is the patient actually using the tool?), symptom progression, side effects or technical difficulties, and other parameters relevant to clinical follow-up. These data, always with the patient's explicit consent, can be transmitted back to the prescribing physician to inform follow-up.

The fifth step is clinical follow-up and therapeutic adjustment. The physician receives information on the patient's progress, typically through dashboards integrated into the electronic health record or automated periodic reports, and assesses whether the digital therapy is producing the expected results, whether the patient maintains acceptable adherence, whether there are adverse effects, or whether it is necessary to adjust the dose (frequency of use), switch to alternative therapy, or supplement with other interventions. Digital prescribing is not an isolated event but the start of a dynamic therapeutic process that requires continuous monitoring, just as would occur with any chronic pharmacological treatment.

17.3.2 THE INVISIBLE INFRASTRUCTURE: INTEGRATION AND STANDARDS

The technical integration of digital prescribing into existing health information systems represents a considerable challenge that is frequently underestimated by application developers.

Digital prescriptions must be able to be generated directly from the electronic health record interface that the physician already uses, without the need for parallel systems that increase the workload. They must be interoperable with dispensing platforms—, public app stores, and institutional health portals—using recognized data exchange standards. They must also allow for the secure bidirectional flow of follow-up data from the patient's app back to the physician's clinical system.

This integration requirement calls for common technical standards that are still under development in many jurisdictions. Well-designed APIs that enable communication between heterogeneous systems; standardized digital prescription formats; authentication and authorization protocols that ensure that only legitimately prescribed patients access therapeutic versions; and integrated electronic billing mechanisms are infrastructure components that require coordinated investment among developers, health systems, and regulators. In countries such as Germany, where the DiGA model has been in operation for several years, specific infrastructure has been developed to facilitate this integration, including centralized directories of approved applications, prescription verification and platforms, and standardized data reporting systems.(2) Other markets are still building these capabilities.

17.3.3 NEW SKILLS AND NEW RESPONSIBILITIES

For physicians, digital prescribing adds powerful tools to their therapeutic arsenal, but it also imposes new competencies and responsibilities that traditional medical training does not always prepare them for. They must develop up-to-date knowledge about which digital therapies are available in their jurisdiction, which have robust evidence for specific indications, which are covered by reimbursement, and what the specific contraindications or precautions are. They must learn to explain these interventions to patients who may have unrealistic expectations about the technology or, conversely, resistance due to digital mistrust. They must develop skills to encourage continued use, recognizing that adherence to digital therapies follows dropout curves similar to those of other chronic treatments. They must be vigilant about unanticipated adverse effects: patient frustration if they do not see quick results, excessive dependence on the app, or “digital fatigue” that reduces long-term effectiveness.

Training in digital prescribing should be a standard component of continuing medical education, not a peripheral option. Medical professional societies are responsible for developing prescribing guidelines, training programs, and certifications that ensure that physicians prescribing digital therapies have the necessary competencies to do so safely and effectively. Hospitals and health systems must integrate digital prescribing into their care protocols, with clinical support decisions that suggest appropriate digital therapies when indicated and with monitoring systems that alert patients to inadequate adherence or suboptimal outcomes.

17.3.4 PATIENT-CENTERED CARE: EMPOWER AND FATIGUE

For patients, digital prescriptions represent both an opportunity for empowerment and a risk of added burden. Digital therapies typically require active participation, time commitment, and cognitive effort that some patients find motivating but others experience as overwhelming. They are not passive interventions such as taking a pill; they are programs that the patient must follow, with tasks to complete, records to maintain, and lessons to integrate. This can be deeply empowering for patients who desire greater control over their condition, but it can be exclusionary for those with limitations in digital literacy, technological access, or the capacity for sustained engagement.

The careful selection of appropriate candidates is an essential part of the art of digital prescribing. Not all patients are good candidates for digital therapies, regardless of the intervention's demonstrated efficacy in general populations. Physicians must assess patients' comfort with technology, their access to devices and the internet, their organizational ability to maintain usage routines, and their personal preference for treatment modalities. Prescribing digital therapy to a patient who does not own a smartphone or who cannot commit to regular use is as futile as prescribing an inhaler to a patient who cannot coordinate inhalation.

The relationship between digital prescribing and treatment adherence is complex and bidirectional. On the one hand, compared with traditional interventions, apps can incorporate gamification elements, smart reminders, immediate feedback, and peer support, which

substantially improve adherence. On the other hand, “digital fatigue” is a real and well-documented phenomenon: after weeks or months of use, many patients lose interest, ignore notifications, and abandon the therapy. The design of effective digital therapies must explicitly incorporate long-term retention strategies: variation in content, adjustment of intensity on the basis of progress, elements of the social community, and a planned transition toward autonomous maintenance.

17.3.5 PRIVACY, SECURITY, AND THE PERSONALIZED FUTURE

Data privacy and security take on critical dimensions in digital prescribing. The data that patients generate while using the therapy—symptoms, behaviors, usage patterns, locations, and interactions—are sensitive health data protected by regulations such as the GDPR or HIPAA, with severe ethical and legal implications if mishandled. The exchange of these data with the prescribing physician must be secured through encryption, explicitly consented to by the patient with an understanding of what is being shared, and strictly limited to what is necessary for clinical follow-up. Patients must retain control over their information, with the ability to review what data have been shared, with whom, and for what purposes and to revoke their consent if they change their mind.

The future of digital prescribing points toward ever-greater personalization through artificial intelligence. Digital therapies will be able to dynamically adapt to each patient's individual characteristics, learning pace, content preferences, and response patterns, modifying protocols in real time to maximize efficacy. Recommendation algorithms can suggest to physicians the most appropriate digital therapy for each specific case on the basis of accumulated evidence from thousands of previous prescriptions. In addition, digital prescribing evolves from a one-time event into a continuous and adaptive process, where the physician adjusts the digital “dose,” frequency of interaction, content intensity, and level of complementary human support on the basis of real-time response data.

For developers of digital therapies, digital prescribing provides the most prestigious and sustainable marketing channel—formal medical endorsement—but imposes design requirements that many consumer applications ignore. Therapies must be designed with integration into clinical workflows in mind, as well as the generation of reports useful to physicians, ease of use for patients with varying levels of digital literacy, and navigation of complex reimbursement processes. They must generate clinical evidence that convinces physicians that incorporating them into their practice is worthwhile and that the results justify the effort of prescription and follow-up. It is a major challenge but also an opportunity to construct products that transcend mass marketing to become genuinely transformative medical interventions.

If we understand the architecture of digital prescribing, the question arises of how these business and intervention models are sustainable in the long term. How do we ensure that digital therapies are not just passing fads but are permanent components of the healthcare system? How do we build technology transfer mechanisms that allow innovations developed in one context to reach populations that need them in others?

17.4 SUSTAINABILITY AND TECHNOLOGY TRANSFER

“The best algorithm in the world, abandoned *owing* to a lack of a maintenance plan, is a monument to failed planning, not a contribution to public health.”

There is a painfully familiar scene in university hospitals and research departments around the world. A multidisciplinary team, combining clinicians, software engineers, and statisticians, spends years developing a genuinely promising prototype: an app that improves glycemic control in patients with type 2 diabetes; a deep learning algorithm for the early detection of diabetic retinopathy; and a decision support system that reduces medication errors in the emergency room. They secure public funding for initial development, publish impressive results in high-impact journals, generate excitement at international conferences, and raise expectations among patients and clinicians. However, when the research project ends, funding runs out, the original researchers disperse to new projects or institutions, and the prototype—which could have benefited thousands or millions of patients—is abandoned in a forgotten code repository, a victim of the lack of a sustainability plan. This unfortunately common story illustrates one of the most serious and least discussed problems in digital health innovation: the persistent gap between successful research and sustainable implementation that truly improves lives.

The sustainability of a medical software project is *ne*; it is neither a fortuitous accident nor an afterthought that can be planned once the product is finished; it is a property that must be explicitly designed from the earliest stages of conception. Sustainability means that the product can remain operational, relevant, and secure over time: updating when new security threats arise or underlying operating systems change; correcting errors when they are detected; adapting to changes in clinical practices and technological standards; and evolving to incorporate improvements on the basis of user experience. This means that there is a business or funding model that generates sufficient revenue or resources to cover these ongoing costs or an institution that explicitly and permanently assumes responsibility for maintenance. This means that there is a dedicated team, with institutional continuity, that has a deep understanding of the product and the capacity to evolve it. Without this built-in sustainability, even the most technically brilliant product is doomed to accelerated obsolescence and eventual abandonment, becoming a dead digital asset that takes up space on servers but provides no value to anyone.

17.4.1 FOUR PILLARS OF SUSTAINABILITY

The first pillar of sustainability is technical. Software, unlike pharmaceuticals, is not a stable chemical entity that remains unchanged over time; it is a complex system that interacts with constantly evolving technological ecosystems. It requires continuous maintenance: fixing bugs that emerge under unforeseen usage conditions, critical security updates in response to newly discovered vulnerabilities, adaptation to new versions of mobile or desktop operating systems that render previous ones obsolete, and integration with hospital information systems that evolve their interfaces and protocols. Many research projects dramatically underestimate these recurring maintenance costs, budgeting only for initial development and running out of resources when the first compatibility or security issues arise. Realistic technical planning must include, from the outset, conservative estimates of annual maintenance costs—typically between fifteen and twenty-five percent of the initial development cost—and an explicit strategy to secure these resources: maintenance contracts, subscriptions, committed institutional funding, or hybrid models.

The second pillar is organizational. The product needs a clear institutional “home”: a commercial company, a nonprofit foundation, or a dedicated hospital department that formally assumes responsibility for its continuity. This involves fundamental decisions regarding intellectual property, governance structures, and institutional leadership. Who makes strategic decisions about the product’s future? Who is legally and financially liable if serious problems arise? Who decides on the incorporation of new features, expansion into new indications, or withdrawal from the market when it is no longer viable? Without a defined and stable organizational structure, the product becomes orphaned, vulnerable to the shifting priorities of institutions that never formally committed to its maintenance, and exposed to discontinuation when the key individuals who supported it leave the project.

The third pillar is financial. The product requires predictable and sufficient revenue streams to cover the operational costs of maintenance and development. This revenue can come from multiple sources: direct product sales, institutional subscriptions, pay-per-use licenses, maintenance service contracts, public grants for sustained innovation and research, transactional research funds, or institutional support from hospitals or universities that consider the product strategic to their mission. The critical factor is that these revenues are diversified whenever possible and predictable over time. Relying exclusively on public research funding is inherently unsustainable in the long term because these sources are temporary by design, geared toward generating new knowledge rather than maintaining existing systems, and subject to political and budgetary cycles that do not respect the continuity needs of medical software.

The fourth pillar is humans. The product needs people who know it in depth, who are capable of diagnosing complex problems, and who can evolve it without breaking existing functionalities. Staff turnover is among the greatest risks to the sustainability of medical software. When the original developers leave—for other projects, other institutions, or other industries—tacit knowledge regarding design decisions, technical trade-offs, and edge-case behaviors is irretrievably lost, and maintaining the product becomes exponentially more difficult and risky. That is why it is crucial not only to thoroughly document the code and architecture but also to build teams with planned continuity, with onboarding processes that systematically transfer knowledge, with succession plans for critical roles, and with an organizational culture that values evolutionary maintenance as much as innovative development.

17.4.2 TECHNOLOGY TRANSFER

Technology transfer is the process by which a product developed in an academic or clinical research environment—driven by publication requirements, temporary funding, and proof-of-concept objectives—transitions to a sustainable production environment where it can be maintained, scaled, and benefit broad populations. It is a complex process involving legal, financial, organizational, and human dimensions and is, unfortunately, the point at which many promising projects meet their premature end—the “valley of death” between successful research and a sustainable product.

The first obstacle in the transfer is intellectual property. Who owns the source code? The university that employs the researchers? The hospital that provided the data and clinical context? The individual researchers who wrote the code? The company that partially funded the project through a research contract? Without legal clarity on the ownership of exploitation rights, it is impossible to negotiate commercial licenses, sell the product, seek venture capital investment, or even continue development in an organized manner. Research transfer offices (RTOs) at universities and hospitals exist precisely to help resolve these issues, but too many projects reach them too late, when ambiguities have already generated conflicts among stakeholders or when commercial windows of opportunity have closed.

The second obstacle is product maturity. Research prototypes, while functionally impressive in controlled demonstrations, are often far from being robust marketable products. They may have user interfaces that only their creators understand, lack technical or user documentation, be unprepared to scale to thousands of concurrent users, fail to meet regulatory security or privacy requirements, or depend on technological infrastructures that are not sustainable outside the research environment. Transition typically requires substantial “product engineering” work to transform the prototype into a robust, documented, scalable, and compliant system. This work entails significant costs that are rarely funded by original research grants and requires industrial software engineering skills that are not always available on academic research teams.

The third obstacle is real-world validation. A product that demonstrated efficacy in a controlled study with selected patients and optimized conditions has not necessarily been proven to work in actual clinical practice, with diverse users, varied contexts, and less-than-ideal conditions. Translation requires implementation studies that evaluate effectiveness under real-world conditions, adaptations to environments different from the original, and potentially new regulatory validations if the indication or target population is expanded. This additional validation process takes time—months or years—and money and resources that are not always available once the original research funding has ended.

The fourth obstacle is the shift in mindset from a research-driven approach to a business-driven approach. Researchers are accustomed to thinking in terms of hypotheses, publications, and contributions to public knowledge. Successful translation requires people with expertise in marketing, sales, financial management, customer service operations, and competitive strategy. It requires understanding the potential market, analyzing existing and emerging competition, identifying viable distribution channels, and building relationships with payers and regulators. Above all, it requires a mindset focused on long-term sustainability, return on investment, and the generation of measurable commercial value—which can conflict with the academic values of openness and public contribution to knowledge.

The fifth obstacle is managing the team. The researchers who developed the product may not be the right people to manage its commercialization: they may lack entrepreneurial skills, prefer to continue researching new ideas, or be unwilling to take on the risks and full-time commitment required to launch a company. Technology transfer often requires bringing in new managerial and commercial talent or licensing the product to an existing company with established commercialization capabilities. This can lead to emotional tensions and conflicts of interest if not managed with transparency and clear agreements from the outset regarding roles, compensation, and ownership.

17.4.3 TRANSFER MODELS

There are different models for technology transfer, each with its own advantages and trade-offs. The spin-off model—creating a new company specifically to commercialize the product—allows for maintaining ties with the original researchers, who typically retain equity stakes and advisory or executive roles and offers maximum flexibility to seek external investment,

scale operations, and pivot strategies on the basis of market insights. It does, however, require entrepreneurs willing to assume the financial and personal risk of dedicating themselves full-time to the project and the willingness of the originating institution to license or transfer intellectual property rights to the new entity.

The licensing model to an existing company, where the university or hospital transfers exploitation rights to an established company in exchange for royalties or upfront payments, is less risky for individual researchers but offers less control over the product's future. The licensee may decide not to commercialize the product if it does not fit its strategy, may modify it in ways that the original creators do not approve of, or may abandon it if commercial results do not meet expectations. License agreements must be carefully negotiated to include due diligence clauses that require effective exploitation and reversion mechanisms if the company fails to comply.

The institutional adoption model, where the hospital or university decides to maintain the product internally as its own service, can work for products that are highly specific to the institution and strategic to its clinical or academic mission. However, it is rarely sustainable in the long term because healthcare and academic institutions are not organized to operate software businesses: maintenance costs compete with other budget priorities, the lack of external revenue limits the capacity to invest in development, and when budget cuts occur, these nonessential products are typically the first to be sacrificed.

17.4.4 RESPONSIBILITIES AND THE FUTURE OF SUSTAINABILITY

For medical software developers, thinking about sustainability and handover from day one of the project is not pessimism but professional realism. The uncomfortable questions must be asked early on: Who will maintain this when I move on to another project or institution? Where will the resources for maintenance come from when research funding ends? What happens if the hospital decides it is no longer a strategic priority? If these questions have clear answers and contingency plans, the project is likely to move beyond the research phase; if they are ignored, the project is doomed to obsolescence regardless of its technical brilliance.

For clinicians considering the adoption of medical software tools, sustainability is an evaluation criterion that is just as important as proven efficacy. They should explicitly ask: What is the five-year maintenance plan? What guarantees are there that the product will continue to be updated and supported? What happens if the developer company disappears or is acquired? A product without a clear sustainability plan is a clinical risk: it may have uncorrected security flaws, it may stop working when operating systems change, or it may become obsolete relative to evolving standards of care. Caution regarding "orphaned" products is a professional responsibility.

The future of digital health sustainability depends on greater professionalization of technology transfer within academic and clinical institutions. Technology transfer offices are gaining experience, resources, and clear mandates to facilitate the transition from research to impact. Investment funds specializing in digital health are emerging that understand the sector's long cycles and complex regulations. Acceleration programs are being developed to provide researchers with the entrepreneurial skills and networks needed to launch successful spin-offs. Collaboration between academia and industry is becoming increasingly structured, with cocreation models in which research and commercialization are planned simultaneously from the outset.

The entire digital health innovation strategy: sustainability is not an end in itself but rather the necessary means to ensure that innovations actually reach the patients who need them and remain available for as long as they are needed. An unsustainable product, no matter how effective it may have been in research studies, is ultimately useless for public health. Sustainability is, ultimately, an ethical responsibility toward patients who rely on these tools, toward the professionals who integrate them into their practice, and toward society, which invests public resources in research expecting a return in the form of better health. To ignore it is to doom even the most technically brilliant projects to failure.

However, once we have ensured the technical and commercial sustainability of our product, we face a global regulatory maze where the rules of the game vary dramatically across continents. How do we navigate the landscape of regulatory agencies that determine whether we can market our medical software, under which risk classification, and with what evidence is required?

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