



Digital health in Europe—who is paying for it and why it matters

Digital health manufacturers need to be prepared for multiple routes to reimbursement.

By Lukas Grabner, Richard Secker-Johnson and Alexandra Toader



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Executive summary

Europe offers unique opportunities for digital health, which should make it part of many companies' plans for commercial success. An early step on the go-to-market journey—access and reimbursement—already represents various challenges, given the nascent and heterogenous landscape of policy and legislation guiding reimbursement assessment and decision-making for digital health.

To find answers, the ZS digital health team in Europe combined secondary research with interviews with payers and digital health experts in select European markets. This study identifies specific reimbursement pathways and provides perspectives on when each of them may be relevant, depending on the specific situation.

Key findings include:

- Europe presents an attractive environment for digital health products and solutions—both in terms of overall opportunity and the regulatory environment.
- Access and reimbursement pathways are still very nascent and heterogenous across markets—requiring companies to navigate a very country-specific environment to bring digital solutions to market.
- Digital health native pathways (such as Germany's Digital Care Act, or DVG) tailored for digital health products provide great opportunity for rapid national access and reimbursement.
- Established medtech pathways can often also provide a viable route to organizations—especially in absence of a dedicated digital health native pathway or when looking at high-risk-class devices.
- In situations where no suitable national reimbursement options exist, sub-national agreements with regions, sick funds and select payers provide an alternative to organizations.
- While access and reimbursement is a foundational step, reaching scale through the right go-to-market strategy, as well as patient and healthcare professional (HCP) engagement, represents an equally critical task.



Europe offers multiple paths to digital health reimbursement—but be prepared for them to be winding

Host to some of the most attractive markets for medtech and pharma, the European region has experienced a boom in digital health in the past few years, and especially so during the COVID-19 pandemic. While Europe has always had a more heterogeneous landscape in terms of innovation adoption and degree of digitization, many markets are now making strides to incorporate digital health into daily clinical practice.

Europe offers a unique environment for digital health, which we believe should make it part of many companies' plans for commercial success:

- Its statutory health systems cover large patient populations, if broad reimbursement or adoption can be achieved.
- There are emerging centralized pathways for access and reimbursement.
- There is substantial interest and movement from policymakers to support the advancement of digital health.

Who is paying for digital health? Paths to payer reimbursement

Before we look at how reimbursement works in Europe, it's important to understand the backdrop for this question.

The definition of "medical device" in European markets is rapidly expanding, and the boundaries between technologies are increasingly porous. Our understanding of the format of a "device" is changing from purely physical products to connected medical devices (CMD) and digital-only, software as a medical device (SaMD). Our definition of "medical" increasingly requires strengthening, with some products clearly delivering a clinical outcome, such as digital therapeutics (DTx), but many more wellness-focused consumer products potentially sitting in a gray area.

Regulators are recognizing the lack of clear boundaries between different technologies and are adding more specificity to their regulations: The Medical Device Regulation (MDR) is an umbrella regulation that defines and covers any and all "medical devices" and defines "medical purpose," bringing more rigor to previously less-scrutinized digital health solutions.

National payers, however, are somewhat behind. In most markets, the national bodies that decide on reimbursement through the healthcare system are playing catch-up with advancements in the industry, resulting in a variety of reimbursement pathways across markets.

As we look across the current European landscape, we identify four distinct pathways that digital health companies can pursue for payer reimbursement of digital and connected devices through Europe's statutory health systems:

- **Digital health native pathways:** New, technology-specific access routes tailored for digital health products.
- **Innovation pathways:** Tech-agnostic access routes and/or specific funding pools designed to pay for medical technology innovations that would otherwise not get covered under established pathways.
- **Established medtech pathway:** Pathways that have previously been used for "traditional" (i.e., physical) medtech and can be repurposed for digital health funding.
- **Sub-national funding pathways:** Selective contracts with regional or local payers or providers, scaling to a broader geography once a benefit has been demonstrated.

Our research and discussions with thought leaders show that, while the last route has been the most frequently used to date (and will likely continue to be a key route-to-market), there is increasing momentum behind centralized pathways for select solution types within markets with the greatest digital ambitions. Let's see why through an overview of each route and when it's applicable.

	Digital health native pathways	Innovation pathways	Established medtech pathways	Sub-national funding pathways
Examples	DVG (Germany)*, mHealth (Belgium)	AAC (UK)*, PHRC, PRME, Articles 51 and 54 (France), NUB (Germany), Promising Care (Netherlands)	LPPR listing (France), GKV negotiation DRG (Germany)	CCG negotiations (UK)*, Regional Health Agencies (France), Regional Insurance Funds (Germany), Regional provider networks (Spain, Italy)
Types of products supported	Mainly healthcare apps; can also be CMDs	Various technology formats; products must be innovative	Mainly physical devices, but could be used for SaMDs or CMDs, depending on regulation scope and precedent	All types
Most suitable for	Low-risk (e.g., class I, IIa), patient-driven apps	Products that need a temporary funding solution until they qualify for an established pathway	More complex, medium- and higher-risk (class IIb and above) SaMDs and CMDs	Early stage products with little evidence
Type of clinical evidence expected	Comparative study (DiGA); RCT as gold standard	Varies; RCT as gold standard	RCT typically expected	Varies, can be as low as local pilots

* highlighted in this white paper

DRG=Diagnosis-related groups, Germany, NUB=New and innovative diagnosis and treatment methods (Neue Untersuchungs- und Behandlungsmethoden), PHRC= Hospital Clinical Research Program, France, PRME= Health Economic Research Program, France

Pathway case studies

1. Digital health native pathways

The lead example is Germany's Digital Care Act (DVG), an accelerated reimbursement pathway specifically targeted at patient-focused, low-risk (class I and IIa under MDR) health apps and app-driven CMDs (e.g., sensor plus app systems) that doctors can prescribe to their patients. This category of products is classified as "digital health applications" (DiGAs).

DiGAs¹ have two routes—a temporary and a permanent one. Under the temporary route, a product that meets DiGA criteria, but has limited evidence, can gain preliminary reimbursement for one year as it builds that evidence. This is expected to be a rigorous comparative study (ideally, a randomized control trial, or RCT) to show clinical benefits or other studies on any structural or health-economic benefits (e.g., savings versus the standard of care [SoC], etc.). Under the permanent route, if a product already meets these evidence requirements, it can be fast-tracked for permanent reimbursement in three months.

These two routes come with a rather unique pricing structure. In the temporary route, pricing for the first 12 months is largely manufacturer-driven, within a framework agreement. In the permanent route, there are price negotiations with the GKV, the statutory health insurance in Germany (GKV-Spitzenverband).

The introduction of the DiGA category had an immediate impact, with many digital health manufacturers applying for reimbursement after the law came into effect and many more still planning to do so in the future. The appeal of fast and wide access to the EU's largest market has propelled Germany into the digital health spotlight.

Belgium took a similar approach with its mHealth framework,² a repository of apps classified by levels: M1 (CE marking); M2 (passed risk, safety and interoperability assessments) and M3 (shows clinical and health-economic evidence and achieves reimbursement), with applications for reimbursement recently opened. It remains to be seen how the trajectory for reimbursed products in these two markets will progress, but we do expect to witness more European markets introducing DVG-like pathways in an effort to ease and standardize access for digital health products. In fact, France announced in late 2021 that it intends to introduce a pathway heavily influenced by the DVG framework, with other EU markets expressing similar interest.³

¹"The Fast-Track Process for Digital Health Applications (DiGA) according to Section 139e SGB V, BfArM," https://www.bfarm.de/SharedDocs/Downloads/EN/MedicalDevices/DiGA_Guide.pdf?__blob=publicationFile&v=2

²MHealth Belgium validation pyramid, <https://mhealthbelgium.be/validation-pyramid>

³Tammy Lovell, "France to enable rapid market access for digital therapeutics," Healthcare IT News, Oct. 20, 2021, <https://www.healthcareitnews.com/news/emea/france-enable-rapid-market-access-digital-therapeutics>

What the challenges are for these pathways: DiGAs are still in the learning curve stage, so some key elements will continue to be in flux. For example, pricing was allowed to be largely self-driven in the first year so payers could learn how to evaluate these products. The standard for evidence is also expected to evolve further in the direction of real-world evidence (RWE). This ambiguity is something manufacturers will need to closely monitor.

The main challenge for manufacturers, however, is that getting national reimbursement as a prescribed healthcare app does not translate into national HCP adoption. The fact that a product can be broadly prescribed by all doctors in Germany does not mean that it will. Right now, the chief reason for this is that awareness of DiGAs as a treatment option is very low among HCPs,⁴ who often do not have the level of information and product support needed to get them to prescribe these products in the same way they would a drug.

“The biggest challenge is to make physicians aware of and persuaded to write a prescription for your app. Those who are successful will be those companies that are visiting the physician.”

– Industry representative, The German Medical Technology Association (BVMed), Germany

2. Innovation pathways

One of the prime case studies of using innovation pathways for digital health reimbursement is the Accelerated Access Collaborative (AAC)⁵ in England. The AAC is not, strictly speaking, a reimbursement pathway, but a stakeholder partnership that provides a springboard for rapid adoption of innovations across NHS England. And, ultimately, it drives the decision on the allocation of innovation funding. The AAC is also an umbrella of multiple mechanisms and programs, from early stage (Innovation Accelerator, or NIA) to later stage (Innovation and Technology Payment, or ITP).

⁴ Bitkom Research survey, <https://www.bitkom-research.de/de/pressemitteilung/jeder-vierte-arzt-will-gesundheits-apps-verschreiben> (in German)

⁵ NHS Accelerated Access Collaborative (AAC), “What innovations do we support?” <https://www.england.nhs.uk/aac/what-we-do/what-innovations-do-we-support/>

In general, this rigorous selection process means its output of nationally commissioned products is fairly limited, constrained to only the most promising candidates. For example, while the NHS Innovation Accelerator⁶ supports a good number of fellows (12 in 2021), the AAC's late stage output of products that are ready for national rollout is not very large, with typically only a handful of solutions spearheaded in a given year through the ITP. Certainly when compared to the 20 solutions reimbursed centrally by the DiGA⁷ pathway already, it becomes clear that the AAC cannot be relied upon as the only vehicle for fast and broad digital health reimbursement.

Notable digital health successes with national commissioning through the AAC have been relatively few. One example is HeartFlow, a software for rapid, noninvasive diagnosis of coronary artery disease that was supported through the ITP.⁸ In addition, the AAC runs a dedicated award for artificial intelligence (AI) in healthcare and supports Academic Health Science Networks, which are advancing less-publicized digital health solutions regionally.

“I don’t see the AAC generating a much higher yearly output. It’s not set up that way. If you’re a digital health manufacturer, it shouldn’t be the only route-to-market you rely on.”

– Former digital leader, NHSX and NHS England

What the challenges are for these pathways: Because innovation pathways amount to scale ramp-ups, this means manufacturers are still left with the step of getting national, long-term funding. A product needs to be successful enough within the innovation pathway to ultimately convince payers it should be permanently reimbursed. As with DiGA, getting physicians to be aware of and use the products propelled by these pathways is still a large effort. In the U.K., this adoption gap is part of the AAC’s purpose, as it advertises these innovations internally to physicians and helps manufacturers navigate the NHS maze. Like with the DVG, they are proof that simply getting access does not automatically guarantee adoption.

⁶ NHS Innovation Accelerator (NIA), “Fellows,” <https://nhsaccelerator.com/fellows-and-innovations/>

⁷ BfArM, DiGA Directory, <https://diga.bfarm.de/de> (in German)

⁸ “NHS England to Provide Innovation and Technology Payment (ITP) to Drive Adoption of HeartFlow Analysis in the United Kingdom,” HeartFlow, April 10, 2018. <https://www.heartflow.com/newsroom/nhs-england-to-provide-innovation-and-technology-payment-itp-to-drive-adoption-of-heartflow-analysis-in-the-united-kingdom/>

3. Medtech pathways

The list of products and services approved for reimbursement, or LPPR, in France is most interesting from a digital health standpoint, as it has been used for the reimbursement of a digital health app. Manufacturers of innovative products can apply for branded listing on the LPPR (list of reimbursed devices) at the Medical Device and Health Technology Evaluation Committee (CNEDiMTS). This committee then assesses actual benefits (the SA score) and added clinical value (the ASA score) to determine whether reimbursement is possible and, if so, whether the product is worthy of a premium. The answer is usually yes if the benefits shown are substantial, the added clinical value versus the SoC is substantial, and the evidence is best in class—in practice, today, that means RCTs. At the end of this process, the French Healthcare Products Pricing Committee (CEPS) then sets the price.

“The LPPR doesn’t distinguish between technologies. It could be used just as well for a prosthetic hand as for a medical app. But [the CNEDiMTS] hasn’t yet seen many digital devices use this, so it is just now opening up to the idea and figuring out how to evaluate them and what expectations to set for them.”

—Member, expert physician in digital health, CNEDiMTS, France

This route in France has resulted in little digital health output so far—most notably the late-stage lung-cancer monitoring app Moovcare⁹ (which actually happens to be a relatively low-risk device). The Moovcare app, the first to get this status, is seen as a rarity. The product’s RCT results vastly exceeded expectations compared to the SoC, improving overall survival by seven months. This made its case to the CNEDiMTS very compelling. It is unclear whether this kind of track can be easily replicated.

Encouragingly, the overall direction of this pathway is warming up to digital health, especially when it comes to the evaluation process.

⁹“First health app in the French LPPR list for add-on reimbursement,” Med Tech Reimbursement Consulting (MTRC), Aug. 18, 2020, <https://mtrconsult.com/news/first-health-app-french-lppr-list-add-reimbursement>



What the challenges are with these pathways: While there is promise that we may have centralized, standardized pathways that can deal with all device formats in the future, right now the LPPR, like its other counterparts, isn't necessarily the best equipped for digital health. The obvious challenge with using these pathways at the moment is evidence. If you've made the choice to go this route, you need to either have very compelling evidence or prepare for the fact that it will take two to three years and a solid investment to build it—all while navigating payer expectations. You should plan to engage with payers early and frequently to make sure you can adapt to their desired study design, clinical and health-economic outcomes.

CASE STUDY: MOOV CARE¹⁰ IN FRANCE

On July 29, 2020, Moovcare¹¹ became the first medical application, a class I medical device, to officially achieve national reimbursement status in France.

1. Evidence Generation: Approximately 2 years to gather evidence

- SENTINEL study ran from June 2014–Jan. 2016, presenting results at ASCO 2016

Phase III randomized clinical trial with 121 patients in 2 groups that resulted in median overall survival (OS) of Moovcare of 7.6 months versus SoC (22.5 vs. 14.9 months)

2. Reimbursement: Approximately 3 years to get reimbursed after the CE mark

- Received SA (Actual Benefit): Sufficient for public interest and ASA: III (Moderate) scores when compared to conventional treatment, such as a follow-up visit with imaging and face-to-face medical consultations
- Granted favorable opinion from the CNEDiMTS for registration under LPPR code 1140921
- Reimbursable tariff of approximately €500

3. Outcome

- Used by clinicians in prominent oncology centers in France
- Partnered with BMS, which provided deployment support to HCPs and hospitals

COMPANY PROFILE

Remote patient monitoring for early detection of relapses in patients with lung cancer

Parent company	HQ	Clinical application	Components	CE marking
Sivan Innovation (Private Limited)	France and Israel	Remote patient monitoring for early detection of relapses in patients with lung cancer	Software application to report symptoms	CE certified, class I

¹⁰ Moovcare, web-based follow-up care for cancer patients, <https://www.moovcare.com/>

¹¹ Denise Silber, "Moovcare, first app to achieve reimbursement in France," Doctors 2.0 & You, <http://www.doctors20.com/moovcare-reimbursement-dr-fabrice-denis/>

4. Sub-national funding pathways

Perhaps unsurprisingly, the bottom-up approach to reimbursement is very prominent. The sub-national level is typically the first step in evidence generation, as well as in working out quality, process and user experience issues. It can lead to gaining enough credibility to access the next level of funding.

In France, for example, you can work with regional hospital associations through pilots to build your way to an RCT and eventual national LPPR application two to three years down the road. In Germany, you can negotiate directly with the sick funds. You may be pleasantly surprised at their willingness to fund even some higher-risk, more-complex products. Sick funds were already paying for some of the DiGA DTx apps before they got DiGA reimbursement. The Netherlands, one of the progressive adopters of overall health digitization, also has insurers actively offering digital health to the patients they cover. Menzis,¹² one of the largest, has introduced programs for weight loss through digital health apps.

“The sick funds in Germany were already paying themselves for quite a few of the DiGAs. If you have something more complex, like a class IIb, your best bet is probably to negotiate with individual sick funds directly.”

– Director, largest health insurance fund, Germany

In the U.K., you may not have a choice, as there is no formal national centralized reimbursement pathway, but decentralization of purchasing through clinical commissioning groups (CCGs). The U.K., in particular, provides a good sample of what going sub-national can look like, with many of the U.K.’s most prominent digital health products taking the route of sequential CCG negotiations. Sleepio,¹³ a DTx for insomnia, is one case study. After launching in 2012, it was offered through sleep health programs in the NHS and then benefitted from support from the Innovation Accelerator (part of the AAC) in 2015. Since then, it has had

¹² “UK-based weight management platform expands to the Netherlands,” Changing Health, <https://www.changinghealth.com/article/uk-based-weight-management-platform-expands-to-the-netherlands/>

¹³ Sleepio Project, Oxford Academic Health Science Network, <https://www.oxfordahsn.org/our-work/sleepio-project/>

multiple RCTs, built its adoption out and has expanded to be part of the national program for psychological therapies (Improving Access to Psychological Therapies, or IAPT). It is now available through many CCGs.

This successive buildup approach recently culminated in NHS Scotland's decision to cover Sleepio nationally for all adults through self- or GP-referral, the first case of countrywide provision of a digital therapeutic.¹⁴

What the challenges are with these pathways: This is the easiest path in terms of costs of entry. The evidence and traction local entities expect will be heterogeneous, but less onerous than what is demanded by national pathways. The trade-off that comes with this path is that it takes longer to scale. It is not uncommon for a product to take more than three to four years to go from launch to critical mass, although that may well accelerate now that healthcare systems have become more open to digital health after COVID-19.

If you choose this pathway, it is vital to build and nurture relationships on the ground, encouraging hospital leaders, payers, key opinion leaders and other players to agree to individual pilots or contracts and to raise awareness of the product among their peers. There is a certain snowball effect with this pathway, where, if a manufacturer has managed to secure commissioned work with an influential sub-national entity, they can use that regional credibility and advocacy to effectively approach the next sub-national player.

“There is no common, unified standard for evidence or pricing expectations when dealing with the CCGs. It’s up to you to figure out which ones are more open to your digital health solution and what their individual expectations are, and that may be different when you go deal with the next CCG.”

—Commissioning manager, NHS England

¹⁴ Tammy Lovell, “NHS Scotland provides access to digital therapeutics for anxiety and insomnia,” MobiHealthNews, Oct. 13, 2021. <https://www.mobihealthnews.com/news/emea/nhs-scotland-provides-access-digital-therapeutics-anxiety-and-insomnia>

Conclusion: Why the path to reimbursement matters to market access

In general, whether you are a digital health startup or an established healthcare enterprise looking to develop a digital health product, Europe is an attractive destination for both commercial success and for testing out different route-to-market strategies.

Unlike in pharma and medtech, however, where the routes to market are clearer and more familiar, manufacturers of digital health products have an array of options to choose from, and some of these options are continuing to evolve. This means the answer to how to get reimbursed is not as straightforward for digital health. You need to make strategic choices early on.

If you have existing digital or connected devices in your portfolio or are looking to develop them, there are a few considerations that should be top of mind.

1. Define your value strategy

The first and most fundamental step is to have a clear value strategy. This results from achieving clarity on your solution's value proposition (across patients, providers and payers), and a clear reimbursement narrative mapped to the different stakeholder needs and evidence requirements of the pathway you are seeking to take. For example, sub-national payers in an integrated system (such as a CCG) may be more willing to accept structural, rather than clinical benefits, versus a national payer managing a more-focused budget.

While a clear value strategy is important for all solution types, this need is amplified for solutions such as remote patient monitoring, where the value to the system is inherently broad. In these cases, where there is a more advanced "logic chain" linking your intervention in the patient journey through to clinical or health system benefits, you need to pay close attention to ensure that you are focused on the right benefits and are appropriately providing evidence for payers to recognize the economic and societal impact of your solution.

2. Develop local market access capabilities

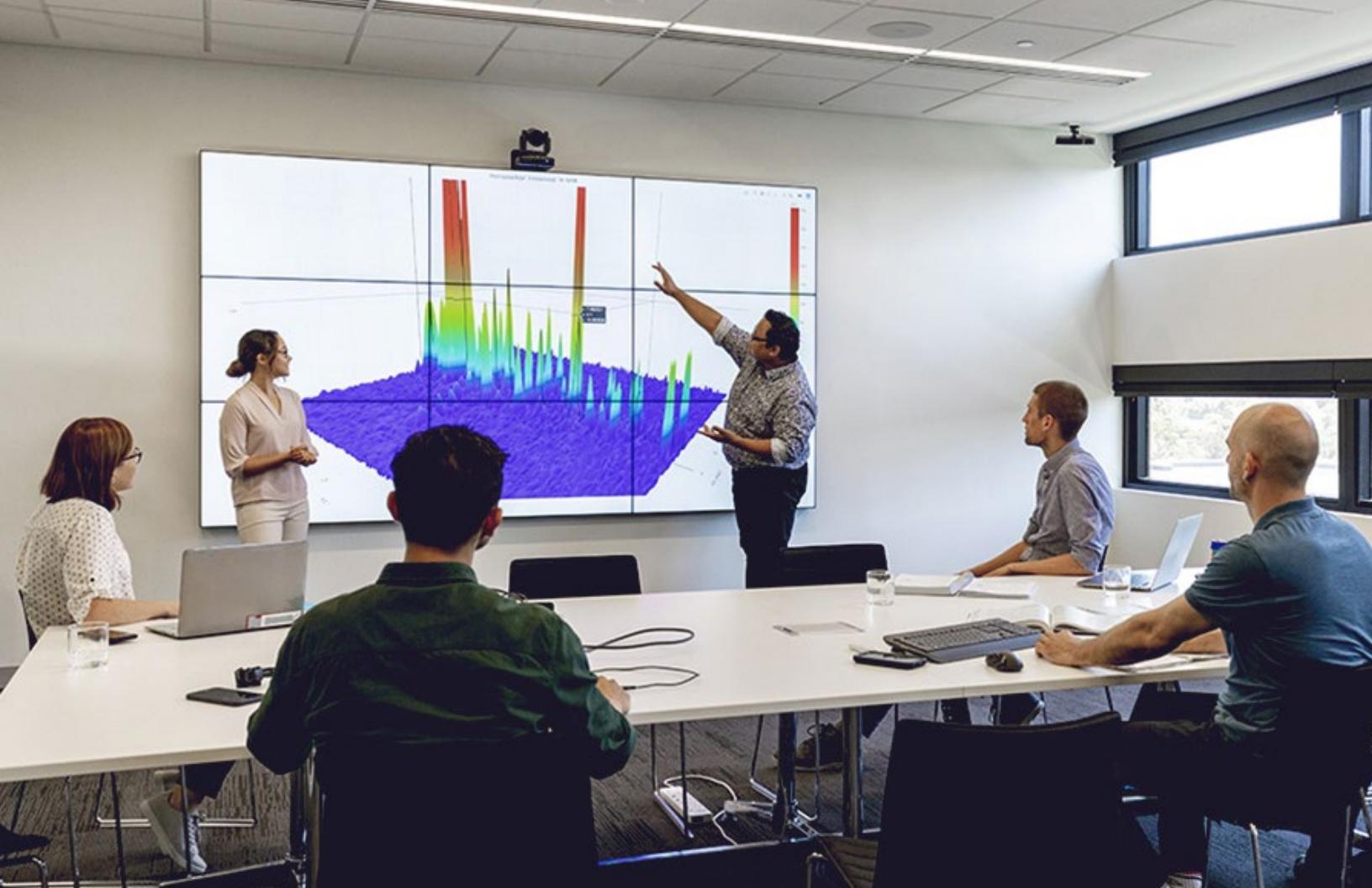
It is evident that market access for digital health in Europe is both dynamic and highly market-specific. While it is theoretically possible to use evidence from one market to also get reimbursement in another, this happens rarely in practice. The navigation of pathways, in general, is still very much a country-level affair. The reliance on the bottom-up route to reimbursement means players with local knowledge and ties have a distinct advantage. Most market access success stories so far, especially for purely digital devices, have come from local players. A key success factor is understanding the funding flows, knowing who the budget holders are and having access to decision-makers in the reimbursement process. These are all locally driven.

3. Map your path-to-scale

Once you have identified the appropriate pathway(s) to pursue, it is important to map your path-to-scale. This will be important in overcoming the scaling challenges that exist across all pathways:

- While national-scale, top-down pathways offer a route toward broad-scale reimbursement, path-to-scale planning is needed to ensure that reimbursement is quickly pulled through to sub-national change in institution and individual provider behavior, helping maintain launch momentum.
- While sub-national, bottom-up pathways offer a means to generate iterative proof of value and demonstrate system integration, path-to-scale planning is needed to ensure that success in one region can be effectively extrapolated across other regions.

In both cases, we recommend developing the path-to-scale in sync with your launch and market entry strategy. This will allow for scaling activities to be put into motion as early as possible, so that appropriate people, processes and tools are ready to support scaling of access and reimbursement when needed. It will also help to inform points-of-entry and launch strategy, for example by ensuring that the first regions targeted in a sub-national pathway are those that will be willing to support the generation and sharing of evidence that initial pilots produce or will be those that are appropriately connected within the scaling networks relevant for your solution type or therapy area (e.g., members of appropriate Academic Health Science Networks, or AHSNs, in the UK).



What matters when it comes to market success

While we have focused on reimbursement, our research has also uncovered broader interrelated themes connected to market success. These topics are inherently complex, but equally important to consider.

Ignore the healthcare provider (HCP) at your peril

Though there is no one answer to the best route to success, one strategy that we do advise against is ignoring the role of the HCP. We see the temptation among digital health businesses to operate under the assumption that, if they can just figure out the consumer or patient angle, they will be successful. While that may be true for DTC-only products, that is adamantly not true for any product that you would hope to eventually see reimbursed through the healthcare system. Unlike consumer tech, in health tech, the HCP (as intermediary) tends to play a more important role in decision-making than the end user.



If the aim is to get a product prescribed or even recommended by physicians, the HCP needs to know that product. They need to know what it does, whom it's for, why it's better than others and where to go if they or the patient have a question. This is self-evident, but it poses a significant issue for digital health products because, unlike drugs or long-established physical devices, HCPs do not have familiarity with them.

In pharma or medtech, that familiarity is achieved through extensive commercial outreach teams and education. This is where established corporate players have home-field advantage—they already have access to, relationships with and go-to-market models tailored around HCPs in their region. The challenge digital health product leaders will need to unlock is how to replicate or tap into that kind of physician outreach platform.

In addition to physician awareness, another key barrier to adoption that a digital health product needs to overcome is physician experience. The mechanism through which the time physicians spend on digital health products is accounted for is also evolving. In Germany, physicians can receive additional reimbursement for the time spent on DiGA treatment, while in the U.K., physicians are paid fixed salaries. So, even if a physician is familiar with a DTx or remote patient monitoring (RPM) and sees some clinical value, if the product is cumbersome to use and adds more work for the physician than it delivers in benefits, it is likely doomed to fail.

Recognize that go-to-market strategy goes beyond reimbursement

If there's one undercurrent that we really cannot overemphasize, it is that go-to-market choice is not a trivial matter for digital and connected health products. Whereas a pill or an implant might automatically lead to a certain go-to-market strategy by their nature, digital health is more complex. Reimbursement is only one part of the puzzle in effective go-to-market decision-making, and companies need to be careful to appropriately weigh multiple additional factors.

Our recommendation is to take an integrated approach to go-to-market strategy that considers the full details of the reimbursement strategy as a later step in the decision-making process. Before this, attention should first be given to appropriately defining which customer types and customer segments to target for commercialization, the business model for solution commercialization, which channels to use for scaling and the appropriate selling process. Each of these factors carries the potential to fundamentally alter the reimbursement strategy, and so should be evaluated in parallel.

Closing remarks: The path forward is ever-changing

Market access is a technical and ever-changing part of commercial strategy for any product, and doubly so for an emerging category of technologies like digital health. It is exciting to witness how all stakeholders in European healthcare systems, from providers to payers, are working on getting more digital health products to patients. Yet it is intimidating to navigate those waters as a digital health manufacturer or product leader. For Europe right now, the answer seems to be that opportunity exists and is growing, if one is prepared to put in the work.

About the authors



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