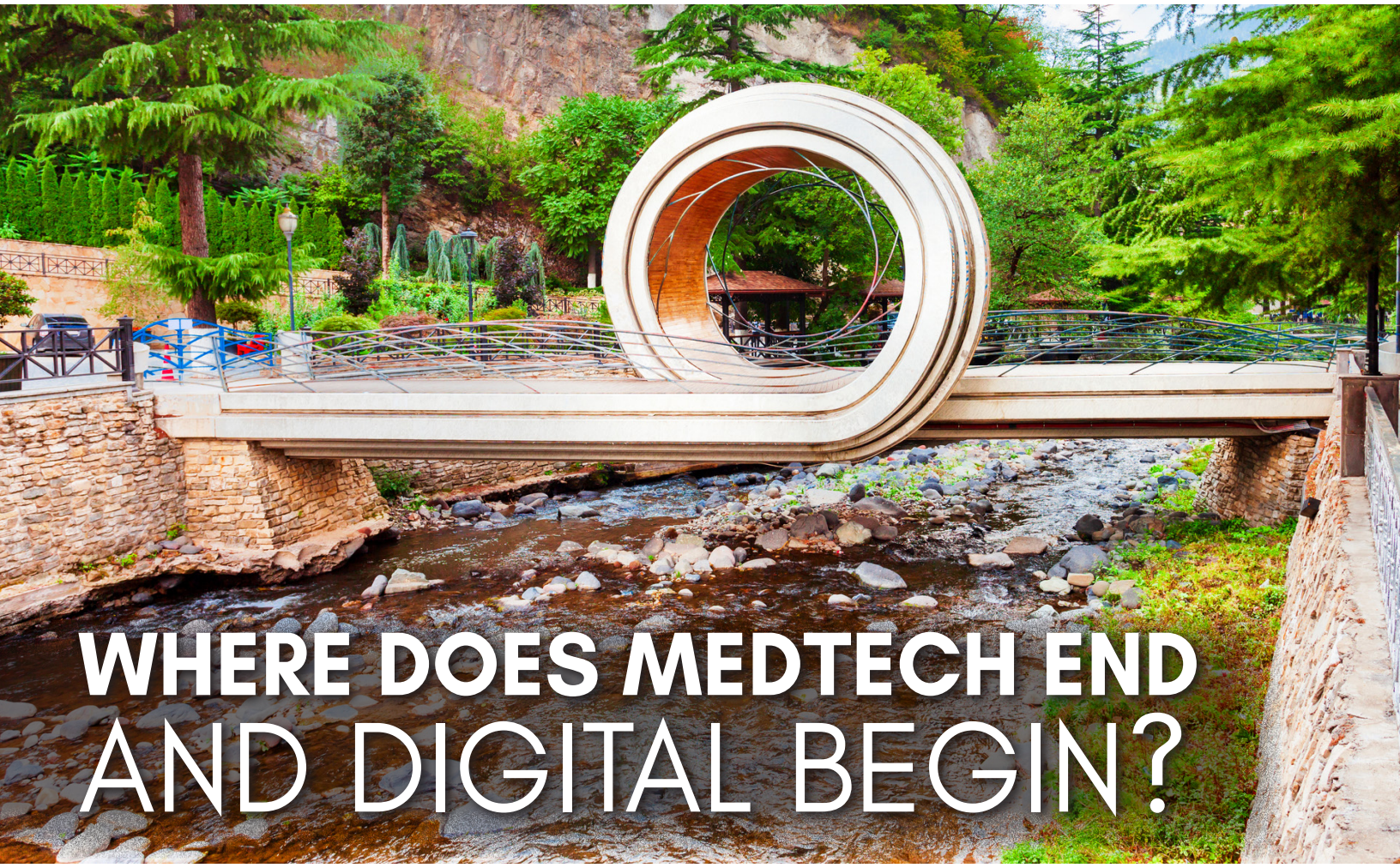


WHERE DOES MEDTECH END AND DIGITAL BEGIN?

The growing pervasiveness of digital tools within medical devices is creating new opportunities to improve care delivery and the benefits are becoming more well-documented. How industry stakeholders should categorize products that leverage this symbiosis, and the implications of categorization, remains a question.

▶ **JOE IVES, SUSAN POSNER, AND JEFF ABRAHAM, HEALTH ADVANCES**

The digital transformation of healthcare is well underway and as the use of software-enabled technologies continues to accelerate, there is an ever-increasing list of ways to classify the solutions being introduced. Some of the more common terms used to refer to the intersection of medical device innovation and IT connectivity are *medtech* and *digital health*. But where does traditional medtech end, and digital health begin? Is there really a line we can draw? The question evokes memories of the early (and classic) Reese's candy commercial—"You got your peanut butter on my chocolate!" "No, you got your chocolate in my peanut butter!" Both multidisciplinary technology categories involve products that rely on combinations of hardware and software for use in reducing clinical inefficiencies, personalizing patient care, expanding physician reach, and reducing costs. While stakeholders

across healthcare recognize the importance of these broader product categories, and continue to invest accordingly, there is very little agreement about how to define these two terms. If we were to attempt to draw a hard and fast line between medtech and digital health, where would that be? Is there an explicit benefit or reason to categorize this new subset of "smart" devices as one or the other? Looking across some innovative product areas you can get a sense of just how difficult the exercise of classification can be:

- Connected spirometers and pulse oximeters
- Fundus cameras with AI-enabled diagnostic capabilities
- Smart spinal cord stimulation (SCS) system
- Continuous glucose monitors

A closer examination of a couple of specific products, like **Zimmer Biomet**'s *Persona IQ* implant and **ivWatch**'s *SmartTouch* sensor, demonstrates how these product categories are becoming inextricably linked. At face value, one would assume that a knee implant brought to market by a leading medical device company is undoubtably medtech. What makes *Persona IQ* unique is that it utilizes a *Smart Stem Extension* sensor that can capture data on range of motion, stride length, and step count. Postoperative data from the sensor can then be viewed by both the patient and surgeon through the Zimmer Biomet *mymobility* Care Management Platform. It would be difficult to argue that the collection and transfer of kinematic data from the sensor to an app-based platform does not qualify in part as digital health.

The growing levels of digitization and connectivity of medical devices can be seen across even more commoditized products. iVWatch, an innovative monitoring company, built an FDA-cleared disposable sensor patch that is taped over IV sites to detect early complications from infusions. This novel solution is designed to help reduce negative patient events (peripheral IV infiltrations, extravasations) by identifying complications earlier and allows clinicians to digitally document IV status during patient assessments. Through the use of its IV administration device and companion patient monitor, iVWatch aims to reimagine and improve a process as established as infusions. In products such as this, traditional medical devices are relying on digital connectivity as a means for differentiation, and as traditional medtech strives for differentiation this trend will continue to gain momentum. As the industry innovates along this continuum, it is important to reflect on the value add. More on that later.

While these products exemplify the overlap between digital health and medtech, there are instances where taxonomy has profound importance. Nowhere is this truth more visible than within the organizations that govern the use of software and hardware in medical devices. As the regulatory center of gravity, the FDA has created through a number of policies unique delineations between purely software digital healthcare products and traditional medical devices. For example, with the introduction of the Software as a Medical Device (SaMD) designation, the FDA established a category of exclusively software medical devices that can operate independently from other equipment or hardware. Although SaMD innovations often work in conjunction with medical devices, there is a separate term for software that requires the use of a device and does not fulfill a medical purpose on its own, highlighting that these classifications tend to fall on a spectrum. Software in a Medical Device (SiMD) is the designation used for software that dictates the mechanics of a medical device or is critical to some other core functionality. As a result of these SaMD and SiMD policies, software and medical device vendors became exposed to entirely new sets of quality guidelines and regulatory requirements pertaining to the application of their solutions. An issuance from the FDA late last month around the use of clinical decision support (CDS) software highlights just how dynamic these policies can be. The final guidance offered in late September suggests that a greater proportion of CDS products, including many that were not previously classified as devices, will be deemed devices and therefore subject to FDA oversight. When developing a healthcare-focused product that relies on software or introduces software to an existing device, it is crucial to understand the implications of these types of classifications, whether the product is viewed as digital health or medtech.

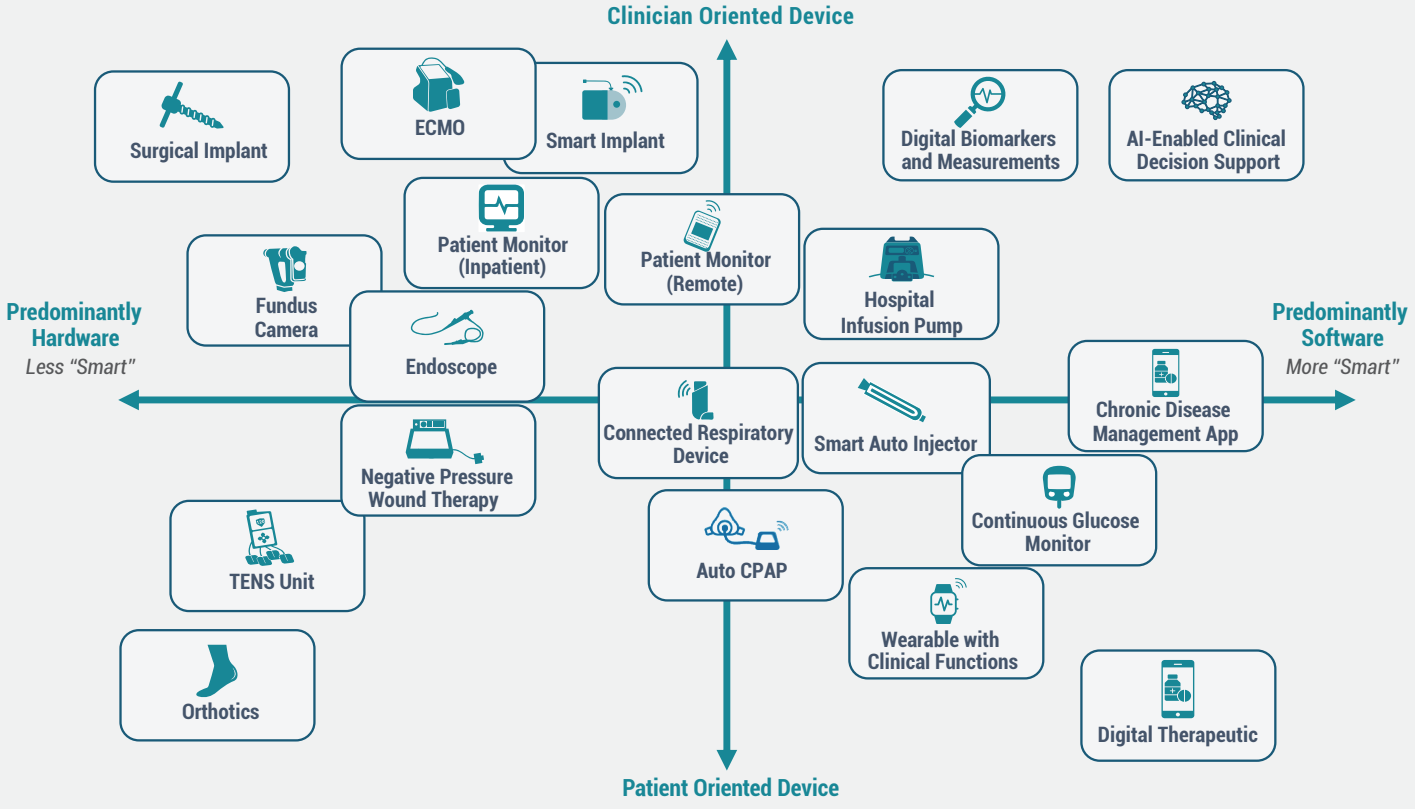
One of the key challenges in compartmentalizing these solutions into specific categories is deciding which criteria should be used to create separation. Individual companies may have a strong sense as to whether they identify as digital health versus medtech, but from the outside looking in, it may be more difficult to categorize. Should determination come down to which vendor is developing the product, whether it is a software company or medical device company? How the product is classified and regulated by the FDA? Or is it about the characteristics of the product itself? For example,

> The ability to apply connectivity to a medical device is not always reason enough to do so. It is essential to identify how a digital component can address an unmet clinical need, improve treatment paradigms, empower patients, impact costs and clinical workflows, or address underlying population health concerns.

a number of traditional medical devices like patient monitors and infusion pumps have long relied on software as a part of their core functionality, whereas some devices are introducing newer, more sophisticated software for additive capabilities. The relationship between hardware and software is shifting as the digitization of medical devices continues, and products often fall on a spectrum across these types of features (see *Figure 1*).

There are a number of broader trends that are contributing to the growing congruence between medical devices and digital technologies. For one, technology is continuing to improve at exponential rates and is no longer prohibitively expensive. Advancements in algorithm accuracy, sensor precision, and the general miniaturization of technology all create opportunities for expanded applications, and in some instances the new and/or improved clinical products bring meaningful clinical benefit. In addition, some of the increased reliance on technology can be attributed to shifts in how healthcare is being delivered. The escalating amount and levels of patient care taking place outside the hospital setting has further necessitated these types of product innovations. As the number of potential use-cases for technology within healthcare increases, it is important to think critically about the value of the tools being introduced. The ability to apply connectivity to a medical device is not always reason enough to do so. It is essential to identify how a digital component can address an unmet clinical

Figure 1
Digitization Drives Hardware-Software Shift



Note: Positioning is intended to be representative and may vary based on specific products.
Source: Health Advances interviews and analysis

need, improve treatment paradigms, empower patients, impact costs and clinical workflows, or address underlying population health concerns. Creating an effective strategy around these types of considerations is paramount for any company bringing a medical device or digital tool to market.

To some extent, every product or device highlighted in this article incorporates software, hardware, and/or services to achieve its desired impact. We at Heath Advances believe that because these types of products touch upon multiple broader categories, it is crucial to incorporate lessons learned and expertise from both medtech and digital health to help realize a product's clinical potential and commercial success. An in-depth understanding of the value propositions of a combined digital health and medtech product that will drive adoption and allow the product to stand out from its peers is crucial. In addition, an effective commercialization strategy including pricing and product positioning, regulatory approvals, coding considerations, and payor adoption is vital to a product's foundation. Deep industry knowledge and experience is required to develop an effective go-to-market plan and achieve adoption across healthcare customers and stakeholders. There are tremendous opportunities for companies that can creatively leverage newer technologies to improve upon existing devices. "Two great tastes that taste great together." Hershey's tagline for Reese's candy in that 1970s commercial holds true for medtech and digital health, and we are excited to see what new, impactful combinations will come from these cognate areas. MTS

Posted on MyStrategist.com Dec. 6, 2022

SUSAN POSNER

JEFF ABRAHAM

JOE IVES

The authors of the article are from the strategy consulting firm, Health Advances. Susan Posner is a partner at the firm and co-leads the MedTech Practice, Jeff Abraham is a vice president and co-leads the Digital Health and HIT Practice, and Joe Ives is a consultant. Founded in 1992, Health Advances is a leading healthcare strategy firm advising clients in the biopharma, device, diagnostic, and health IT sectors. The authors can be reached at MedTech@healthadvances.com or Digital@healthadvances.com.