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DIGITAL HEALTH REFORMULATION: FROM HOPE TO HYPE TO HEALTH

In this article, Chelsea Williams, MPH, Healthcare Analyst; Ramin Rafiei, PhD, Director of Digital Healthcare; and Ralph Howald, MSc, MBA, Chief Technology Officer, all of SHL Medical, discuss the accelerating value of digital health to improve the patient experience, achieve improved health outcomes, and increase health system efficiency and value through the work at SHL.

It would be remiss to fail to acknowledge that over the past decade digital health has not led to mass disruption of how patient care is delivered. In an era where the smartphone will shortly turn 15 years old, and society has moved towards the expectation of on-demand delivery of services and access to all of humanity's knowledge in the palm of their hands, health technology adoption has, by and large, not moved along as fast as some would wish.[1]

We are in a transitory period where digital health is still being positioned within the healthcare landscape – and a myriad of road bumps are being encountered. There are well over 40,000 health and medical apps, yet there are no criteria for what constitutes "good" or "bad".[2,3] Telehealth has much potential to drive patient care but practitioners are slow to adopt and regulations are laborious. Sensors are being added to medical devices but we are still not seeing them applied well clinically.[4]

Finally, everyone gravitates towards artificial intelligence in healthcare, while the greater barrier – health information – still faces the difficulty of interoperability to gather and interpret. In many ways, the digital health story needs to change – and the time is upon us as the field meets maturity.[5]

> "In many ways, the digital health story needs to change."

HOPE VERSUS HYPE

Looking back over the past decade's worth of keynotes, presentations and publications on digital health, it would be hard not to empathise with the hope of what digital health could have led to in patient care. The use of technology to lower barriers to access and improve health outcomes, all the while making care affordable, were all items championed for this digital revolution. Healthcare providers saw an opportunity to improve patient care, and the pharmaceutical industry saw novel opportunities to conduct clinical trials and expand clinical outcomes. Nonetheless, this hope arguably led to much hype that was misplaced by technology-focused newcomers to the health space with no experience or insight to succeed.

As an example, look at the story of Theranos, headed by a Stanford dropout. Once valued at US$10 billion (£7.9 billion), Theranos achieved national acclaim at the forefront of development for blood testing.[6] Its appeal – a highly usable product that could disrupt the blood-testing industry – was irresistible to many interested in the health space. But, in the end, the real utility of Theranos was non-existent, and it is probably one of the best examples of the hype of digital health technology that can grab global attention along with fast cash investments, yet fail to deliver.

Difficulties can be seen across the digital healthcare industry, where there is no shortage of companies over the past decade that pursued aggressive growth metrics then

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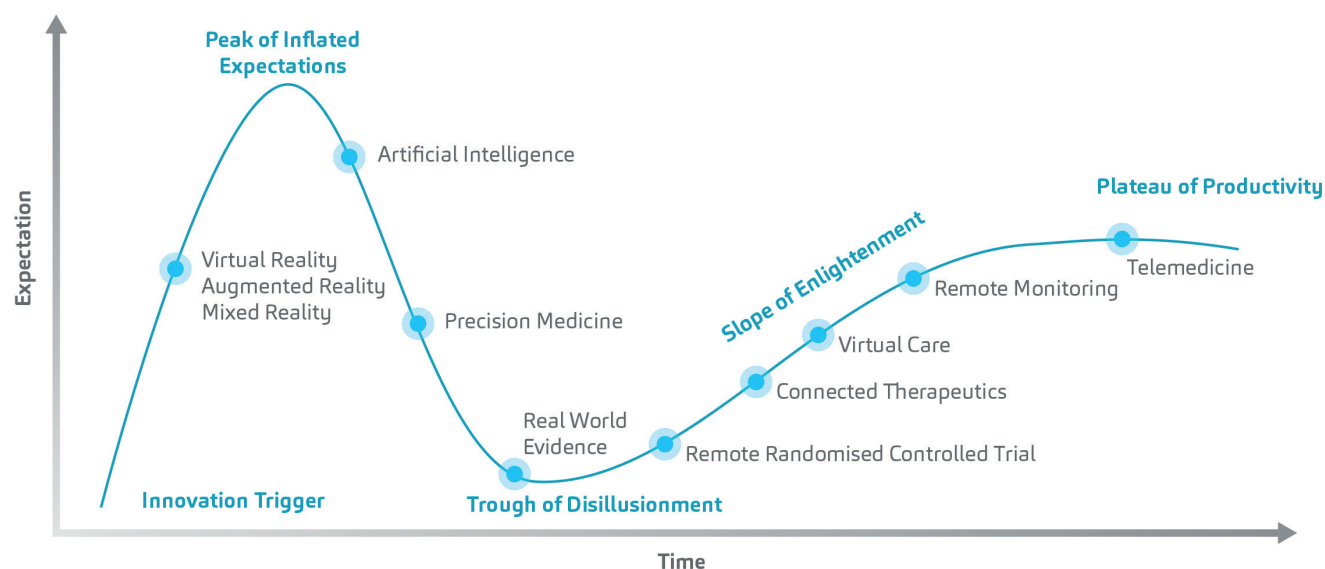Gubelstrasse 22
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Figure 1: The digital health hype cycle, adopted from the Gartner Hype Cycle.

"Merely creating a digital tool of yesterday's practice for tomorrow's care, and expecting uptake, is a fallacy."

collapsed, whether focused on a mobile app or novel sensor-based technology. The impact has been comparatively mute in the grand scheme of health, and it is still difficult to point to a mobile app and claim it meaningfully shifted how health is delivered.[7]

Undeniably, one of the most significant issues has been a focus on creating and providing a product that naïve founders expected patients and healthcare providers to flock towards. This "innovation without integration" is likely one of the most notable missteps in the digital health space, as many companies focused on disruption over integrating with current medical practice which, despite much hype, is more realistically a slower-paced environment of change.[8]

However, like other industries that have undergone digital transformation, health companies have matured with the realisation that digital health is here to stay but will need a thorough mindset and ideology to achieve it in practice.

TO DELIVER WITH DIGITAL HEALTH

A paradigm shift in how care is delivered does not occur overnight and, arguably, the practice of medicine is grounded in the realm of science, which expects the rigor of evidence-based decision making founded on well-constructed trials and data supporting best practice. Merely creating a digital tool of yesterday's practice for tomorrow's care, and expecting uptake, is a fallacy in

thought. As such, a well-designed product needs to meet multiple criteria to escape the hype cycle of digital health (Figure 1) and yield actual health outcomes.

Digital health is transitioning the drug delivery industry towards connected therapeutics. Over the past three decades, SHL has set the foundation for the decentralisation of drug administration. Complex treatments have graduated from focusing solely on safety and efficacy to acknowledging the importance of patient convenience and adherence.

The parenteral drug delivery innovation curve (Figure 2), illustrates the evolution of drug delivery from a simple vial and syringe (A) to the convenience and safety of an autoinjector (B). The addition of sensors and connectivity now provides a digital representation of patient behaviours, by enabling dose-level data collection (C). Ultimately, innovation in drug delivery matures to connected therapeutics (D), which allows patients to self-manage their conditions as part of their integrated care plans – pairing health with technology.

This move from self-administration to self-management relies on patient activation, engagement and retention to ensure a successful transition towards a decentralised, continuous and proactive model of care delivery.

The ubiquity of connected drug delivery devices, as a precursor to connected therapeutics, will empower better

behaviours and minimise care errors, as well as delivering timely clinical support. However, this will be an untenable goal without factoring in crucial concepts that have led to the hype cycle (Figure 1) which has plagued other companies competing in the digital health space. Instead, a focus on three pillars of thought – usability, usefulness and utility – is essential for the realisation of connected devices, and subsequently connected therapeutics.

HAVE USABILITY

A key aspect of product design is factoring in the usability of a product by the ultimate consumer. For instance, the initial rollout of the iPhone used skeuomorphism to help new users become accustomed to mobile apps as their go-to tools. Since this rollout, the growing convenience, responsiveness and hyper personalisation delivered by top technology brands and their integration into other industry sectors has created an expectation for digital health to deliver the same experience.

The inability to meet this expectation has rendered the majority of digital health programmes ineffective. Drugs don't work in patients who don't take them; similarly, digital health programmes don't work for patients who don't engage with them. Take, for example, the sheer number of wearables and mobile apps on the market, which sees a substantial dropout in use after just a few weeks of initiation. In one study looking at engagement with 93 popular mental health apps currently available, less than 10% of users were still retained after one month of downloading the app.[9] Finding the right design to get a patient engaged in digital tools is a science under development.
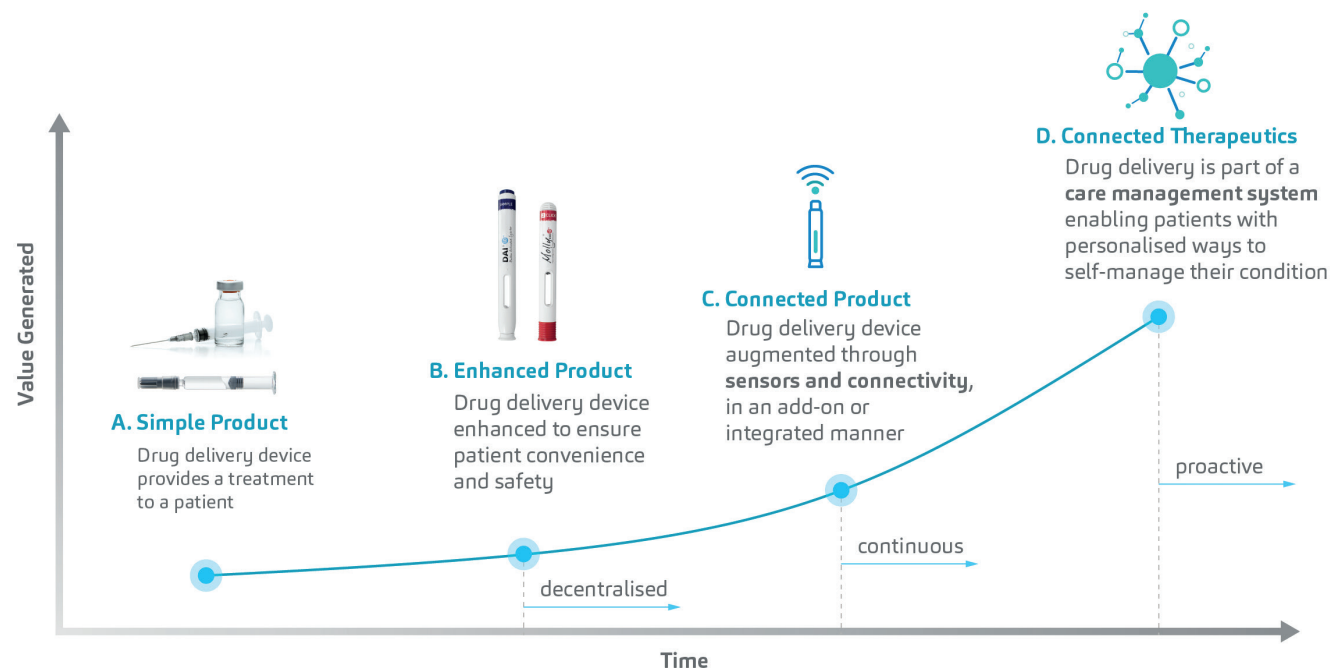
Figure 2: The parenteral drug delivery innovation curve.

The ubiquitous needle and syringe have been encapsulated by the autoinjector market as a viable means to be a more natural fit for medication administration. But the creation of such a product takes effort, patient-centric design studies, human factors design and continuous feedback. As the drug delivery industry transitions towards connected therapeutics, the same experience will be required to consider these aspects and design products that succeed. Simply adding Bluetooth-enabled sensors to a product will not yield a product of worth if users cannot put it to use.

Therefore, taking into consideration how a patient uses the product – such as setting it up, interpreting their own data (e.g., adherence, routes, timing) – will be tantamount to increasing user engagement in their own personal health. In many ways, the usability of a product can lead to a personalised level of care that can be leveraged by pharma and healthcare providers to drive the outcome change needed at this time. Lessons learned by a company to create safe, engaging, convenient and autonomous devices will be a knowledge base for digital health development.[10,11] Nonetheless, a usable product means nothing if it is not useful.

BE USEFUL

Deriving the usefulness of a product is perhaps one of the most notable weaknesses of early digital health products. We have seen multiple iterations where an Internet of Things (IoT) strategy was used to upgrade a conventional health device into a digital health product. These include wearable devices that are merely an updated pedometer or blood

pressure cuff capable of collecting vital information in the patient's home – or even smart pill bottles that can subjectively track adherence and yet did not change patient outcomes.

Several trials that hypothesised the use of digital tools would yield significant patient outcomes such as reduced hospitalisations, meeting target goals and increasing patient safety, failed to demonstrate their clinical endpoints. The BEAT-HF study evaluated the impact of remote patient monitoring (RPM) in reducing rehospitalisation amongst patients recently discharged with an acute heart failure exacerbation.[12] More than 1,400 participants were evaluated for 180 days, using Bluetooth-enabled devices to track relevant patient data – yet rehospitalisation rates saw no statistical difference with the intervention compared with standard care.

Similar results can be found in other RPM studies looking at apps and devices to manage blood pressure in that they have also failed to meet their clinical outcomes.[13,14] Perhaps even more tragic is that, in an analysis of 280 diabetes apps for self-management, only 11 apps were found to have data supporting clinical value – and, of those, only five demonstrated a significant impact on HbA1c (glycated haemoglobin).[3]

Possible reasons may stem from a lack of judicious use of this novel technology as we continuously learn how best to enrol and have patients use the devices, and for health practitioners to then direct therapeutic care with real-time data acquisition. After all, this is a change in medical practice where digital health takes us from intermittent data

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collection towards real-time care. Patients are consumers; hence adaption does not occur overnight and the industry is bound to see multiple failures.

The nature of science, and the medical literature as a whole, benefits from these failures as it helps educate organisations about what to improve upon.[15] Companies that have invested significant resources into understanding clinical workflows, patient adherence characteristics and behavioural interventions to maximise their impact will have a higher likelihood of succeeding in this evolving market.

We are now seeing this maturation built upon, as different stakeholders – such as medical practitioners and pharma – are finally taking note. The American Medical Association, for example, has created a digital health group focused on helping physicians use novel tools to adopt clinical care for the next decade. This includes topics such as remote patient monitoring and telemedicine, which were increasingly needed as a result of the COVID-19 pandemic that has swept the world this year.

Indeed, the pandemic will perhaps go on to be one of the largest game changers in the digital health industry, as healthcare providers turn to remote patient monitoring and communication to treat patients, while pharma learns to adapt to an environment it never had to face.[16,17] For years, the topic of remote patient trials has seen much discussion, with few companies going beyond pilots or small feasibility trials.[18,19] The current limitations in logistics, with patients social distancing, will increase the need for digital health technologies in clinical trial design and will need to be stress tested.

Consequently, companies that offer novel solutions and technology may serve as apt partners for pharma to consider.[20] Companies will need to be prepared to pivot to this sudden need and cultural shift due to sweeping changes occurring across the world as patient care delivery changes.

FIND UTILITY

Utility is healthcare economics. Demonstrating the utility of a product and service will be the final pillar to see digital health completely gain acceptance in the market. Whether this includes a push for value-based care using digital health tools, whereby healthcare providers view such devices and software as a means to maximise patient outcomes, or payers see digital health as a data-driven resource to improve their covered populations, remains to be seen.[21]

Providers of healthcare services and payers do not always share the same perspective as patients. Accordingly, a digital health product that may be beneficial to a provider may not be something a patient finds useful (or even usable). Likewise,

a digital health product that addresses a patient need may not find traction with a payer or provider, requiring the patient to pay out-of-pocket. Even if a product itself addresses usability and clinical evidence shows it is useful, if it doesn't find utility within the financial interests of all stakeholders, then adoption will be limited and even the most revolutionary technology will not realise its potential.

Digital health isn't going away any time soon. Using the Gartner Hype Cycle, as adapted to digital health (Figure 1),[22] we see that market demand for demonstration of utility squeezed out many early players – leaving only those companies with a longer-term vision and healthcare industry experience. We could view the past decade as the peak of inflated expectations, with the past few years as the trough of disillusionment and the 2020s as a period of enlightenment towards productivity.[23] This can be seen with market changes where over 60% of digital health companies pivot from business-to-consumer (B2C) to business-to-business (B2B) or B2B2C solutions, as they were developed in the vacuum of the tech sector, and applied a tech strategy which is not transferable to the idiosyncrasies of healthcare.[24]

Ultimately, companies and organisations are becoming aware of the need for evidence generation through randomised controlled trials (RCTs) and real-world evidence (RWE) to convince payers of the utility of their digital health products.[25,26] This calls for large resources and experience to accomplish what smaller organisations cannot accomplish alone.[27] Research and development spending for creation of new products,[28,29] and research to discover novel digital biomarkers, guide clinical care.[30,31]

However, commercialisation can only be achieved once these most basic hurdles are crossed and become data driven. Ultimately, this will incentivise healthcare providers and pharma to integrate such digital health products into their patient care management and disease treatment solutions in ways that we could never do in the past.[32-34] It may also spur novel developments in relationships between pharma and payers, such as performance-based, risk-sharing agreements based on collected data.[35] This is reinforced with a growing focus on developing digital health formularies for health systems and payers to adopt, with clinical evidence and usability data key for inclusion.[36]

REFORMULATING DIGITAL HEALTH

The term digital healthcare will become synonymous with healthcare in the future, and current terminology will be relegated as a marker to this transitory period of healthcare evolution.[37] Nonetheless, this will be an uphill battle that will play to first-mover advantage for those that take on the risk of innovation.[38] Pharma has yet to achieve its "beyond the pill" moment but the current *status quo* should not dissuade it from trying. Instead, key partnerships will be essential for bringing digital health to fruition.

At SHL Medical we are accelerating the evolution of drug delivery from a focus on patient self-administration towards a holistic patient-centered self-management paradigm across a spectrum of chronic diseases and conditions (Figure 3).

In transforming our patient-centric drug delivery devices to life-centric therapeutic solutions, we have shifted focus to the whole patient-journey by combining innovation in drug delivery with innovation in disease management. This will ensure we meet the disease management needs of our pharmaceutical partners, through new means to track and utilise the data that was previously not available in the injectables market. Innovation in disease management will lead to innovation in care management as patients become more informed, empowered and engaged with their treatment. Anticipating this demand, our care management solutions are currently undergoing validation within a randomised, controlled trial setting, focusing on the patient's individual needs, and creating personalised and tailored care pathways that can be delivered continuously and remotely.
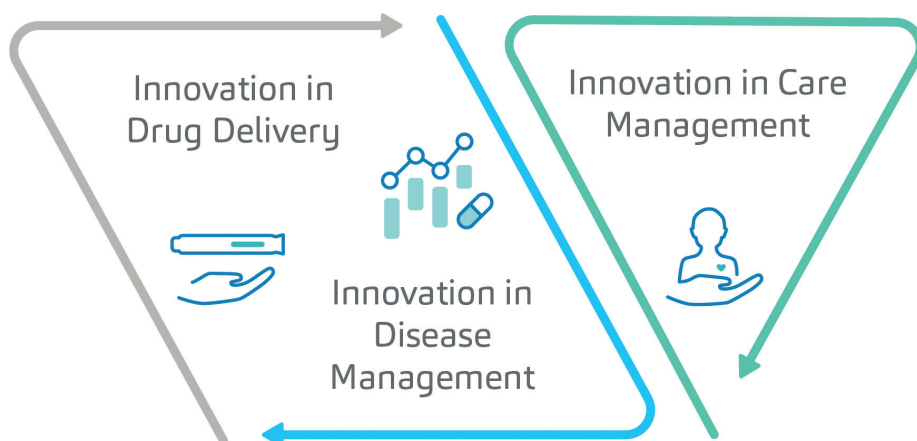

Figure 3: Digital health innovation at SHL encompasses drug delivery, disease management and care management.
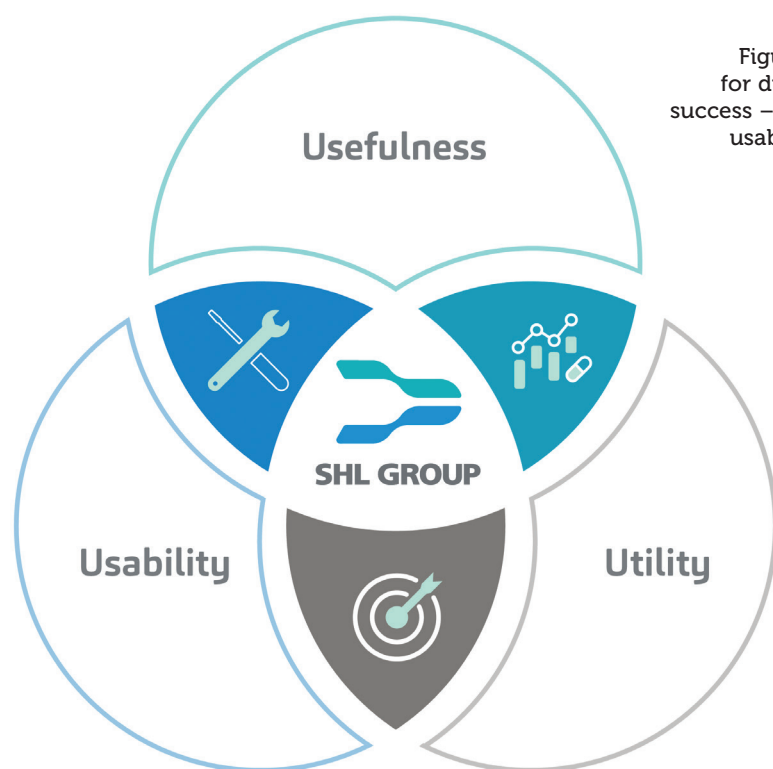
Figure 4: Goals for digital health success – usefulness, usability, utility.

Our passion and work in ensuring that our products are usable and useful – and can be utilised across the healthcare industry – is a formula for digital health success (Figure 4). As we scale our digital health investments this decade, and expand our partnerships, we will continue to capitalise on an innovation culture which has brought three decades of industry-shaping leadership. This next decade of digital healthcare innovation towards connected therapeutics is well and truly underway.

"Our passion and work in ensuring that our products are usable and useful – and can be utilised across the healthcare industry – is a formula for digital health success. As we scale our digital health investments this decade, and expand our partnerships, we will continue to capitalise on an innovation culture which has brought three decades of industry-shaping leadership."

ABOUT THE COMPANY

SHL Medical is a world-leading solution provider in the design, development, and manufacturing of advanced delivery devices such as autoinjectors, pen injectors, and advanced inhaler systems. With locations in Taiwan, Switzerland, Sweden, China, and the US, our experienced engineers and designers develop product enhancements as well as breakthrough drug delivery and patient care solutions for pharma and biotech clients globally. Significant investment in R&D has enhanced our broad pipeline of next-generation drug delivery systems that support ongoing innovations in drug development and digital healthcare. This includes advanced reusable and disposable injectors that can accommodate high volume and high viscosities and can be enhanced through digital implementations.

REFERENCES

1. "Digital Health Consumer Adoption Report 2019". Rock Health and Stanford Center for Digital Health.
2. Gordon WJ, Landman A, Zhang H, Bates DW, "Beyond validation: getting health apps into clinical practice". NPJ Digit Med, 2020, Vol 3, pp 14.
3. Veazie S, Winchell K, Gilbert J et al, "Rapid Evidence Review of Mobile Applications for Self-management of Diabetes". J Gen Intern Med, 2018, Vol 33(7), pp 1167–1176.
4. Caulfield B, Reginatto B, Slevin P, "Not all sensors are created equal: a framework for evaluating human performance measurement technologies". NPJ Digit Med, 2019, Vol 2, pp 7.
5. Sim I, "Mobile Devices and Health". N Engl J Med, 2019, Vol 381(10), pp 956–968.
6. Fiala C, Diamandis EP, "The meteoric rise and dramatic fall of Theranos: lessons learned for the diagnostic industry". Clin Chem Lab Med, 2018, Vol 56(9), pp 1443–1446.
7. Safavi K, Mathews SC, Bates DW, Dorsey ER, Cohen AB, "Top-Funded Digital Health Companies And Their Impact On High-Burden, High-Cost Conditions". Health Aff (Millwood), 2019, Vol 38(1), pp 115–123.
8. Cohen AB, Martin SS, "Innovation without integration". NPJ Digit Med, 2020, Vol 3, pp15.
9. Baumel A, Muench F, Edan S, Kane JM, "Objective User Engagement With Mental Health Apps: Systematic Search and Panel-Based Usage Analysis". J Med Internet Res, 2019, Vol 21(9), e14567.
10. Domańska B, Stumpp O, Poon S, Oray S, Mountian I, Pichon C, "Using Patient Feedback to Optimize the Design of a Certolizumab Pegol Electromechanical Self-Injection Device: Insights from Human Factors Studies". Adv Ther, 2018, Vol 35(1), pp 100–115.
11. Bittner B, Schmit Chiesi C, Kharawala S, Kaur G, Schmidt J, "Connected drug delivery devices to complement drug treatments: potential to facilitate disease management in home setting". Med Devices (Auckl), 2019, Vol 12, pp 101–127.
12. Ong MK, Romano PS, Edgington S et al, "Effectiveness of Remote Patient Monitoring After Discharge of Hospitalized Patients With Heart Failure: The Better Effectiveness After Transition -- Heart Failure (BEAT-HF) Randomized Clinical Trial". JAMA Intern Med, 2016, Vol 176(3), pp 310–318.
13. Persell SD, Peprah YA, Lipiszko D et al, "Effect of Home Blood Pressure Monitoring via a Smartphone Hypertension Coaching Application or Tracking Application on Adults With Uncontrolled Hypertension: A Randomized Clinical Trial". JAMA Netw Open, 2020, Vol 3(3), e200255.

14. Morawski K, Ghazinouri R, Krumme A et al, "Association of a Smartphone Application With Medication Adherence and Blood Pressure Control: The MedISAFE-BP Randomized Clinical Trial". JAMA Intern Med, 2018, Vol 178(6), pp 802–809.

15. Hicks JL, Althoff T, Sosic R et al, "Best practices for analyzing large-scale health data from wearables and smartphone apps". NPJ Digit Med, 2019, Vol 2, pp 45.

16. Torous J, Jän Myrick K, Rauseo-Ricupero N, Firth J, "Digital Mental Health and COVID-19: Using Technology Today to Accelerate the Curve on Access and Quality Tomorrow". JMIR Ment Health, 2020, Vol 7(3), e18848.

17. Ting DSW, Carin L, Dzau V, Wong TY, "Digital technology and COVID-19". Nat Med, 2020, Vol 26(4)., pp 459–461.

18. Steinhubl SR, Wolff-Hughes DL, Nilsen W, Iturriaga E, Califf RM, "Digital clinical trials: creating a vision for the future". NPJ Digit Med, 2019, Vol 2, pp 126.

19. Bakker JP, Goldsack JC, Clarke M, et al, "A systematic review of feasibility studies promoting the use of mobile technologies in clinical research". NPJ Digit Med, 2019, Vol 2, pp 47.

20. Marra C, Chen JL, Coravos A, Stern AD, "Quantifying the use of connected digital products in clinical research". NPJ Digit Med, 2020, Vol 3, pp 50.

21. "sigma 1/2020: Data driven insurance". Swiss Re Institute, January 29, 2020.

22. Price L, "Digital Health Hype Cycle 2020". Healthcare.Digital, April 10, 2020.

23. Klonoff DC, King F, Kerr D, "New Opportunities for Digital Health to Thrive". J Diabetes Sci Technol, 2019, Vol 13(2), pp 159–163.

24. Evans B, Shiao S, "Streamlining Enterprise Sales in Digital Health". Rock Health.

25. Klonoff DC, Gutierrez A, Fleming A, Kerr D, "Real-World Evidence Should Be Used in Regulatory Decisions About New Pharmaceutical and Medical Device Products for Diabetes". J Diabetes Sci Technol, 2019, Vol 13(6), pp 995–1000.

26. Dickmann LJ, Kothare PA, C"an Digital Health Enable Higher Quality Real-World Evidence-Based Decisions?". Clin Pharmacol Ther,
2019, Vol 106(1), pp 45–46.

27. Noah B, Keller MS, Mosadeghi S et al, "Impact of remote patient monitoring on clinical outcomes: an updated meta-analysis of randomized controlled trials". NPJ Digit Med, 2018, Vol 1, pp 20172.

28. Marra C, Chen JL, Coravos A, Stern AD, "Quantifying the use of connected digital products in clinical research". NPJ Digit Med, 2020, Vol 3, pp 50.

29. Coravos A, Doerr M, Goldsack J et al, "Modernizing and designing evaluation frameworks for connected sensor technologies in medicine". NPJ Digit Med, 2020, Vol 3, pp 37.

30. Coravos A, Khozin S, Mandl KD, "Developing and adopting safe and effective digital biomarkers to improve patient outcomes". NPJ Digit Med, 2019, Vol 2, pp 40.

31. Mahadevan N, Demanuele C, Zhang H et al, "Development of digital biomarkers for resting tremor and bradykinesia using a wrist-worn wearable device". NPJ Digit Med, 2020, Vol 3, pp 5.

32. Kourtis LC, Regele OB, Wright JM, Jones GB, "Digital biomarkers for Alzheimer's disease: the mobile/
wearable devices opportunity". NPJ Digit Med, 2019, Vol 2, pp 9.

33. Baker M, Beek JV, Gossens C, "Digital health: Smartphone-based monitoring of multiple sclerosis using Floodlight". Nature Research.

34. Kerr D, King F, Klonoff DC, "Digital Health Interventions for Diabetes: Everything to Gain and Nothing to Lose". Diabetes Spectr, 2019, Vol 32(3), pp 226–230.

35. Yu JS, Chin L, Oh J, Farias J, "Performance-Based Risk-Sharing Arrangements for Pharmaceutical Products in the United States: A Systematic Review". J Manag Care Spec Pharm, 2017, Vol 23(10), pp 1028–1040.

36. Aungst TD, Vogenberg FR, "Digital Health: A New-Age Spectrum of Therapeutics". PT, 2019, Vol 44(11), pp 691–693.

37. Steinhubl SR, Topol EJ, "Digital medicine, on its way to being just plain medicine". NPJ Digit Med, 2018, Vol 1, pp 20175.

38. Mathews SC, McShea MJ, Hanley CL, Ravitz A, Labrique AB, Cohen AB, "Digital health: a path to validation". NPJ Digit Med, 2019, Vol 2, pp 38.

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The SHL Perspective

Empowering Transformation

Capitalizing on an innovation culture which has brought three decades of industry-shaping leadership, we continue to improve patient quality of life through initiatives in drug delivery, as well as disease and care management.

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