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SELFCARE SOLUTIONS

DIGITAL SELF-CARE – SOLVING PATIENT CHALLENGES WHILE DELIVERING ROBUST THERAPY DATA TO PHARMA

Here, Stefanie Seiler, PhD, Product Manager Digital Health, and Ventsislav Dobrev, Global Lead Digital Health, both at Ypsomed, discuss self-care challenges for patients and highlight how Ypsomed Digital Health's solutions can solve them while also delivering meaningful business insights for pharmaceutical companies.

In today's healthcare landscape, pharmaceutical companies have an opportunity to support patients in a more personal way through digital health solutions. The repercussions of subpar self-care management, such as therapy drop-offs, low patient engagement and low therapy adherence, emphasise the urgent need to empower individuals in their treatment journeys. The potential to improve therapy outcomes by supporting patients in managing their self-care is huge, as an average of 70–80% of patients with long-term conditions opt for self-care in addition to receiving professional care at hospitals.[1]

Patients who struggle to manage their complex diseases may find that digital self-care tools provide the skills they need to monitor and control their treatments more efficiently, as well as to access reliable information and training. Moreover, fully integrated digital health solutions can assist pharmaceutical companies in unlocking valuable insights for R&D, shortening market access timelines and improving commercial success.

MAKING SELF-CARE SIMPLER AND EASIER

Self-care encompasses many components beyond just medicine and medical devices themselves and can be described as the ability of individuals to promote and

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maintain their own health, while coping with their illness.[1] For self-injection therapies, this means that patients need to self-inject correctly, self-monitor their health and become self-aware of changes to their condition so that they can react appropriately and involve healthcare professionals as needed. Digital health solutions can facilitate this by delivering training and guidance about self-care tools and increasing health literacy through easily accessible, accurate and appropriate information. Education in the use of self-care tools is the foundation that enables patients to play an active role in improving their own health.[1] Only self-confident and self-sufficient patients benefit from a better quality of life and the best possible therapy outcome while performing self-care at home.

Ypsomed has been at the forefront of self-care innovation for 40 years, making it simpler and easier by delivering simple-to-use and reliable products to pharmaceutical companies that improve patients' quality

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Figure 1: Ypsomed Digital Health – seamlessly integrated connected devices, patient apps and data analytics.

"The future of self-care is on."

of life. Ypsomed Digital Health's solutions consist of seamlessly integrated connected devices, patient apps and data analytics tools (Figure 1). Ypsomed's fully integrated digital ecosystem supports pharmaceutical companies in delivering self-care solutions to patients that improve adherence rates, therapy outcomes and quality of life, while also unlocking business-changing insights for themselves. Ypsomed has achieved this by expanding its experience in self-care with S3 Connected Health (Dublin, Ireland) and Sidekick Health (Kópavogur, Iceland), two leading digital health partners – the future of self-care is on.

SOLVING PATIENT CHALLENGES IN SELF-CARE

Key Self-Care Challenges for Patients

"I was panicked when I picked up the medication! There was no one to explain it. I have to do everything. I'm sick, and then I have to play my own nurse? I am lost", "I had to search for information about what to do if anything went wrong by myself. How can we be expected to do this alone?" and "I'm not taking this medication anymore and I haven't told my doctor because he won't agree with me" are just a few statements from patients reflecting the difficulties that countless individuals living with chronic conditions experience while navigating their self-care journeys.[2,3]

To ensure that Ypsomed understands the various patient needs and delivers products that resonate with the target audience, the company regularly engages with patients to understand their experiences in self-care with and without digital solutions. Ypsomed uses techniques such as prototype testing, cognitive walkthroughs, think-aloud interviews, formative human factors testing and clinical feasibility studies in standard of care. The results from these studies, together with literature-based research, have enabled the company to identify five key patient challenges in self-care:[1–3]

- **Complex treatment regimens** overwhelm patients
- **Lack of information and education** hinders correct self-care and building of correct self-injection rituals
- **Low self-efficacy** due to lack of training
- **Low self-confidence** fuelled by fear of forgetting something
- **Negative mindset** towards therapy caused by injection anxiety and psychological distress.

Understanding patient needs helps Ypsomed to identify potential product improvements, such as interface and navigation adjustments for step-by-step injection support, logbook access and overall therapy management. These findings are systematically integrated into the company's product development process, from start to finish, by shaping design choices and feature implementations – ensuring that its solutions meet the diverse needs of patients.

Personalised Support for Optimal Self-Care with Convenience

Ypsomed Digital Health equips patients with the appropriate tools, such as (connected) self-injectors, connected add-ons and a patient app, empowering them to manage their complex therapies. User-friendly interfaces allow patients to access learning platforms, resources and helpful guidance, supporting the seamless integration of self-care into their lives. The patient app has an integrated behavioural engine that allows for personalised training to improve self-efficacy and smooth onboarding to the therapy. Interactive step-by-step injection guidance during the injection process allows for proper application and provides real-time feedback of handling errors that may occur, in addition to giving patients the self-confidence they need to manage their therapy. The app supports patients in finding their own injection ritual by offering different tools, such as relaxation techniques, breathing exercises or music, to overcome potential injection fear. This personalised support on an as-needed basis provides consistent reminders and support throughout the treatment, thus leading to a positive mindset over the course of the therapy.

Enable Self-Care Through Caregivers

Not all patients wish to self-inject and self-manage their therapy, either because of their condition or by choice. This is where caregivers can step in and play a pivotal role in at-home care. Some conditions are complex, and friends or family members may choose to share the burden of caring for a loved one. However, ensuring therapy adherence and correct administration requires a significant amount of co-ordination. Allowing for simple care co-ordination, Ypsomed Digital Health's solutions connect all the caregivers for each patient. Everyone involved can see symptom progression and logbooks, have access to disease or therapy information and step-by step user guidance, and receive treatment reminders.

SOLVING PHARMACEUTICAL COMPANIES' CHALLENGES WITH DIGITAL HEALTH SOLUTIONS

Leveraging an Existing Fully Integrated Digital Health Ecosystem

Digital health solutions are ideally well adopted by patients, caregivers and healthcare providers, and facilitate R&D, market access and commercial success for pharmaceutical companies, ultimately simplifying life for everyone involved. To achieve this, all tools – such as drugs, devices, patient apps and data analytics – need to be fully integrated into a single ecosystem. If not delivered by

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one provider, pharmaceutical companies can waste a significant amount of time, resources and money, and are faced with huge co-ordination efforts to develop and maintain such an ecosystem. Moreover, these multi-provider setups increase the risks for lifecycle management, which can include maintenance issues and unclear roles for end-to-end solution verification, validation and operations. Ypsomed delivers fully integrated end-to-end digital health solutions (Figure 1), including connected devices, patient apps and data analytics, allowing pharmaceutical companies to focus on their core business. Ypsomed Digital Health's solutions are based on a disease-agnostic platform that is scalable and can be customised to brands, diseases and patients' specific needs while ensuring efficient lifecycle management and maintenance.

Facilitating R&D with Robust and Objective Data for Evidence Generation

The rapidly growing adoption of pragmatic study designs and decentralised clinical approaches – expected to be incorporated in 90% of studies in 2024 – depicts the current trend for faster and lower cost clinical trials that allow patients to participate from wherever they are without the need to travel.[4] Ypsomed Digital Health's solutions support robust data collection during these trials by capturing objective injection data, such as date, time and results of the injection, on the connected device. Through the digital ecosystem, these data are related to other data points, such as therapy schedules and recordings of side effects, delivering information that can be analysed for the early detection of potential safety issues and adherence rates. In the case of low adherence, corrective measures such as automated reminders, personal follow-ups, or additional training and education can be implemented to reduce the risk of losing patients during follow-ups.

By studying the relationship between drug exposure and response, the dose regimen and benefit-risk ratio can be optimised. Additionally data captured from electronic patient-reported outcomes and quality of life questionnaires can help understand the drug's impact on patients' lives beyond traditional clinical endpoints. The data can be leveraged for trial design planning by, for example, identifying profiles for high-risk participants or participants that are more likely to respond to the treatment,[5] ultimately generating evidence faster and at a lower cost with improved data quality.[5]

Facilitating Market Access with Robust Real-World Data for Health Economics

Digital health solutions may provide data that supplement clinical trial evidence and fill the gaps in understanding drug performance in diverse patient populations or under real conditions, thereby accelerating market approvals. In 2017, for example, the US FDA used real-world evidence in the form of a historical control arm to grant marketing approval of Merck and Pfizer's avelumab for treating Merkel cell carcinoma. Also, in 2019, Pfizer's palbociclib, previously only approved for treating women with ER+/HER2-breast cancer, was approved in men based on real-world data related to its off-label use among men.[6]

Moreover, the data can be used in health economic models to demonstrate a drug's value in improving patient outcomes, reducing healthcare use and lowering overall costs, thereby supporting reimbursement decisions by payers. The agreement between UPMC Health Plan and Boehringer Ingelheim is one example of a value-based pricing model, linking the reimbursement of Boehringer Ingelheim's Jardiance® (empagliflozin), an oral Type 2 diabetes medicine, to the total costs of care for all patients treated for diabetes.[7] In 2022, 58% of the surveyed payers in the US had at least one outcome-based contract in place, where reimbursement is tied to predefined clinical outcomes, performance metrics or therapy adherence.[8]

Facilitating Commercial Success and Insights into Patient Population Behaviour and Market Dynamics

By incorporating digital health solutions into their commercial and launch strategies, pharmaceutical companies can enhance the value proposition of their drugs, differentiate themselves in the market and, ultimately, improve patient outcomes, leading to better brand loyalty, greater commercial success and sustained market presence.

The insights gathered by digital health solutions can help pharmaceutical companies to understand patient journeys by analysing real-world behaviour. Learning how patient behaviour can differ within a specific subset of the population facilitates tailoring solutions to specific patient populations for better solution
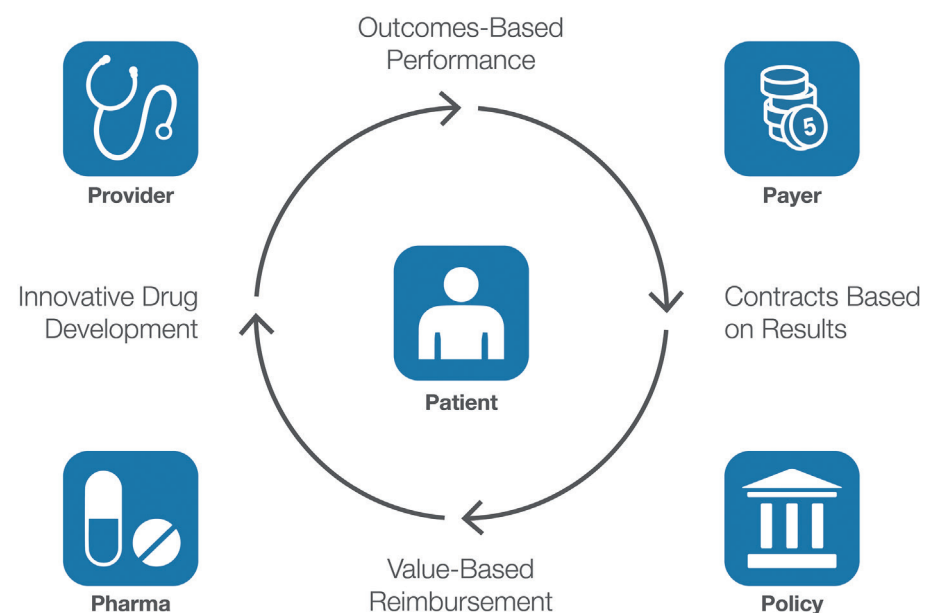

Figure 2: Digital health solutions provide benefits to all stakeholders of the healthcare system.

adoption and higher therapy adherence. Moreover, understanding geographical differences in solution usage and adoption can help apply best practices from one area to another, ultimately generating more revenue for the asset.

CONCLUSION

Digital health solutions have great potential to support patients in a more personal way, empowering their self-care journeys. However, for digital health solutions to be economical, the drugs, devices, apps and data analytics need to be connected in a fully integrated ecosystem that is scalable and provides benefits to all stakeholders, including patients, healthcare professionals, caregivers, pharmaceutical companies, payers and policy makers (Figure 2).[9]

ABOUT THE COMPANY

With 40 years of experience, Ypsomed is a global pioneer for the development and manufacturing of innovative, simple-to-use, reliable self-injection devices and digital health solutions for pharmaceutical and biotech companies, which contribute significantly to the success of therapies – making self-care simpler and easier.

Ypsomed supplies customisable product platforms for autoinjectors for prefilled syringes in 1 and 2.25 mL format, disposable pens for 3 and 1.5 mL cartridges, and reusable pens that include automated injection mechanisms.

The injection systems are developed and manufactured in Switzerland with strong in-house competencies covering concept and product development, toolmaking, injection moulding and automated assembly. Ypsomed is ISO 13485 certified, and all processes are run according to design control and cGMP guidelines, with operational quality assurance and control experts on-site at each location. Ypsomed's devices are supplied to global markets including the US, Europe, Japan, China and India.

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Stefanie Seiler, PhD, is Product Manager Digital Health at Ypsomed. She has eight years' experience in healthcare focusing on clinical research, real-world data and digital health solutions. In her previous position, she closely collaborated with all stakeholders of the healthcare system to develop a nationwide real-world data platform to improve therapy outcomes for patients. Dr Seiler holds a PhD in Biomedical Sciences from the University of Bern, Switzerland.

Ventsislav Dobrev, Global Lead Digital Health, is a pharmacist by training with specialisations in digital health, health informatics and population health. Mr Dobrev has more than 20 years of experience in healthcare across different domains and an intrinsic passion as to how technology can empower patients for self-care.