BRINGING DIGITAL HEALTH AND DRUG DELIVERY TOGETHER TO SUPPORT SUBCUTANEOUS INJECTION IN ONCOLOGY

Here, Damien McKeon, Senior Vice-President Global Alliances and Strategic Partnerships at Aptar Digital Health, and Sueyoung Yoon, Digital Solution Lead at Gerresheimer, discuss the trends driving interest in subcutaneous administration, the barriers to overcome and the characteristics of a patient-centric solution.

Ongoing advances in drug development are bringing to market highly targeted therapies for treating cancer or autoimmune disorders that can be administered subcutaneously instead of intravenously. Subcutaneous injection offers advantages that include faster and less invasive administration, and the potential to facilitate patient self-administration. That said, factors such as resistance to change, disruption of patient flows through the health system and the difficulty of addressing highly variable side effects may stand in the way of adoption.

That is why patient centricity is an important consideration for any organisation developing therapies for self-administration. Beyond the device itself, pharmaceutical companies should seek to support patients by leveraging digital health solutions to guide them through self-administration, symptom management and communication with their healthcare providers. Building intuitive and scalable digital health solutions is critical to overcoming common barriers to self administration and bringing valuable therapies to more patients in need.

THE TRENDS DRIVING INTEREST IN SUBCUTANEOUS ADMINISTRATION

Three important trends are driving both care delivery by healthcare providers – and pharmaceutical companies to develop subcutaneous administration modes. Here, subcutaneous refers to the injection of a medication into the fatty tissue just below the skin, most commonly on upper arms or thighs or on the belly between the ribs and hips.[1]

First is an improvement in clinical efficacy at a lower cost. Subcutaneous injections enter the body through fatty issue, not the bloodstream, which makes administration less invasive and a preferred administrative mode for patients.[2] Dosages are smaller for subcutaneous injections compared with intravenous, which reduces the likelihood of severe side effects. Finally, subcutaneous doses can be administered in minutes, compared with hours for intravenous injections.

Closely linked to clinical efficacy is the goal of providing a more patient-centred care experience. Along with the potential

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for a better physical response to treatment, subcutaneous administration may reduce the amount of time patients need to spend in a clinical setting. Plus, as treatment progresses, patients may become more comfortable with self-administration in their own homes, with clinical visits reserved for routine follow-ups or acute care needs. For many patients, these improvements represent a stark contrast to the hours they spend in clinic receiving an intravenous injection and the negative side effects they experience[3] – common factors that may influence a patient to interrupt or discontinue treatment.

The third trend is increased interest in reformulating and repositioning existing immunotherapies. Developing new drugs is costly, time-consuming and risky. This is especially true for rare conditions – the complexity of drug development, coupled with the small patient population impacted, can lead to very high market prices for a pharmaceutical company to achieve a return on investment. The process of reformulating and repositioning previously approved therapies for new indications or new forms of administration presents fewer obstacles than *de novo* development.[4]

FOUR COMMON BARRIERS TO EMBRACING SUBCUTANEOUS ADMINISTRATION

Although these trends present clear advantages to pharmaceutical companies, healthcare providers and patients alike, there are four main reasons for stakeholders to be cautious about the transition to subcutaneous administration:

1. **The reorganisation of patient pathways:** Patients receiving subcutaneous injections may not need to visit a hospital's infusion centre. As a result, healthcare providers may have fewer opportunities to see patients in person and therefore may have less insight into how patients are progressing. More broadly, for healthcare providers operating under volume-based payment models, such as in the US, a decrease in foot traffic into an infusion centre may be perceived as a business threat due to diminishing revenue.
2. **A reluctance to change administration methods:** Both patients and healthcare providers may be unwilling to transition away from intravenous injections. Amid something so familiar – the visit to the clinic, the administration process, the effectiveness of the treatment and the side effects – the drawbacks of a new treatment experience may be perceived to outweigh the benefits.
3. **The potential unpredictability of toxicity:** The side effects of subcutaneous injections can be difficult to predict. They may take longer to present, as the therapy does not enter the bloodstream immediately and can vary significantly depending on mechanism of actions. Some patients may choose to discontinue subcutaneous injections altogether, while those who stay on subcutaneous treatments will require close home-based monitoring of symptoms and side effects.
4. **A significant increase in data for healthcare providers to handle:** Monitoring patients' symptoms and side effects generates a large volume of data – both structured data from devices and unstructured data from patient-reported outcomes. Healthcare providers may be reluctant to receive, process and view this data, especially if they are used to directly observing patients in an infusion centre in the hours following an intravenous injection.

While these barriers are by no means insurmountable, they do suggest pharmaceutical companies need to take a thoughtful approach to drug development. In addition to the therapeutic itself, they need to consider how and where it will be administered, what data needs to be gathered during and after administration, and how that data should be presented to healthcare providers.

THE CHARACTERISTICS OF A PATIENT-CENTRIC SOLUTION

The key to an approach that considers how a drug is administered and how healthcare providers engage with it is patient centricity. Pharmaceutical companies need to frame subcutaneous administration from the perspective of how it can benefit patients. Critically, this approach must apply not just to the workflows and solutions they develop for patients; it should also guide how they deliver data, insight and support to healthcare providers.

Challenge	Features of Patient Centricity			
	Remote Monitoring	Training and Onboarding	Self-Management	More Useful Data
Reorganisation of patient pathways	Insight into a patient's condition outside the clinic	Relieve burden of transitioning to new workflows	Empower patients to do more on their own	Insight into which patients need care only clinic can provide
Resistance to change	Ensure providers remain in the loop, reduce cost of unplanned hospital visits[5]	Get providers up to speed, minimise unproductive time	Devote fewer resources to providing low-acuity care	Better longitudinal view of patient outcomes
Unpredictable toxicity	Track symptoms and side effects in real time	Help patients know what to expect, when to seek help	Where appropriate, help patients address symptoms on their own	Gain long-term view of efficacy and side effects to inform future care decisions
Influx of data to providers	Share the most relevant data in a usable format	Show providers how to act on data and insights	Let providers focus on patients who cannot meet needs on their own	Help providers address concerns, not just observe them

Table 1: Challenges and features of a patient-centric solution.

There are four general features of a patient-centric solution for subcutaneous administration:

1. **Remote monitoring** lets healthcare providers track patients' adherence to treatments and/or symptoms from home. This offers insight into efficacy as well as potential side effects while reducing the expense and carbon footprint of frequent patient trips to the clinic.
2. **Training and onboarding** guides patients and clinical staff through the administration process. Educational materials can help to explain the type and severity of anticipated side effects, while on-demand training offers ease of use and can support patients during their moments of need.
3. **Self-management support**, such as video tutorials and subcutaneous injection training devices, can build patients' confidence in self-administration. This can improve adherence as well as clinical outcomes, which together have a downstream effect of requiring fewer resources to deliver high-quality care.
4. **Smarter, more useful data** give patients and healthcare providers actionable insights, relieving them of the burden of searching through large, often unstructured datasets for relevant pieces of information.

Table 1 (see previous page) summarises how each feature of a patient-centric solution helps to address a different aspect of the challenges of subcutaneous administration.

Ultimately, a patient-centric solution for self-administration is one tha is safe (regulated as a medical device), convenient (simple to use and insightful) and personalised (tailored guidance and resources). That is why the partnership between Gerresheimer and Aptar Digital Health is important for the industry. Integrating state-of-the-art, sustainable drug delivery devices with software platforms for remote monitoring and patient self-management can provide an extension of the clinic within the patient's home, provide greater insight into the progression of treatment and improve the overall care experience.

HOW TO DEVELOP AN IDEAL PATIENT-CENTRIC SOLUTION

A successful patient-centric solution for subcutaneous administration can lead to improvements in the patient experience, medication adherence, clinical outcomes and overall quality of life. In developing such solutions, however, pharmaceutical companies and their technology partners must ensure that patients can make the connection between how they use the solution and how they benefit from it.

If patients feel as though they put more into a solution than they get out of it, they are likely to abandon it. This could result from usability issues such as tedious manual data entry – or it could stem from workflows that inhibit a patient's ability to view their personal records or other resources, communicate with their healthcare providers or otherwise gain insight into their health. On the other hand, if patients feel that a solution is helping them maintain a relationship with their healthcare providers, stay informed about their condition or improve their health, they will likely continue to use it.

One of the most important steps in ensuring this happens is to include patients in the product development process. This should begin at the ideation stage and continue through insights research and validation. Additionally, this should include both formative and summative human factors studies – which, it should be noted, are described in the regulation to be followed by both the US and the European Union.[6] Patients' interactions should not be limited to user experience and human factors testing; security, legal and engineering teams will all benefit from understanding how patients expect to use a solution.

Such a high degree of patient involvement in development can help to ensure a digital health solution can support care pathways in the clinical as well as the "real-world" setting. This will be critical as subcutaneous injections continue to transition to the home-care setting. Meanwhile, ongoing user testing and feasibility testing – even after devices and their accompanying digital solutions have been approved and launched – helps to ensure solutions are intuitive for all patients, particularly those previously unfamiliar with injection devices or mobile applications.

BRINGING TOGETHER INDUSTRY-LEADING SOFTWARE AND DEVICES

In January 2024, Aptar Digital Health and Gerresheimer announced a partnership to develop tailored solutions to support patients and healthcare providers in subcutaneous cancer therapy administration and management (Figure 1). The partnership brings together Aptar Digital Health's expertise in developing software as a medical device with Gerresheimer's innovative on-body device for subcutaneous delivery of large biologic molecules, Gx SensAir®.

Figure 1: Aptar Digital Health and Gerresheimer's partnership.

"The partnership brings together Aptar Digital Health's expertise in developing software as a medical device with Gerresheimer's innovative on-body device for subcutaneous delivery of large biologic molecules, Gx SensAir®."

The integrated solution to be developed as part of this collaboration will integrate Gerresheimer's Gx SensAir® with the Aptar Digital Health software platform. This will allow patients to receive real-time, actionable recommendations as they use the Gx SensAir® and as they track and manage their symptoms. It will also facilitate communication with patients' healthcare providers, allowing them to stay connected with their care teams and helping to reduce their anxiety about self-administration and treatment. Critically, the solution can integrate with dozens of electronic health record systems, enabling healthcare providers to monitor and engage with patients using familiar clinical workflows.

Initially, the integrated solution will be used for therapies such as PD-1/PDL-1 and CTLA-4. These immune checkpoint therapies are proven to be effective at treating certain types of cancer, with similar survival outcomes[7,8] and less severe side effects[9,10] compared with traditional treatments. As is common with immunotherapies, patients often need training. The combination of easy-to-use devices and robust digital guidance and support is positioned to improve the patient's experience, so they remain on therapies longer, achieve better clinical outcomes and have improved quality of life.[11]

Aptar Digital Health and Gerresheimer are confident that this initiative can scale to additional therapies delivered subcutaneously, for cancer treatments as well as other chronic conditions. This will allow many more patients to experience the benefits of subcutaneous administration, and it will have the additional upside of removing much of the treatment burden from care delivery organisations. With both patients and healthcare providers benefiting from the level of support available from self-administration enhanced by digital health, the time is right for broader adoption of subcutaneous injection.

ABOUT THE COMPANIES

Aptar Digital Health creates end-to-end solutions to enhance patient experiences every day, leveraging a holistic ecosystem of digital interventions. Amplified by portfolio of products and solutions, Aptar Digital Health's offering combines mobile and web apps, connected drug delivery systems, onboarding, training and advanced data analytics services to actively empower patients and create a positive treatment journey. Aptar Pharma's Digital Health division is part of AptarGroup, Inc, a global leader in drug and consumer product dosing, dispensing and protection technologies.

Gerresheimer is an innovative system and solution provider and global partner for the pharma, biotech and cosmetic industries. The company offers a comprehensive portfolio of pharmaceutical containment solutions, drug delivery systems and medical devices, as well as solutions for the health industry. The product range includes digital solutions for therapy support, medication pumps, syringes, pens, autoinjectors, inhalers, vials, ampoules, tablet containers and infusion, dropper and syrup bottles, among others. Gerresheimer ensures the safe delivery and reliable administration of drugs to the patient. With 36 production sites in 16 countries in Europe, the US and Asia, Gerresheimer has a global presence and produces locally for regional markets.

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Sueyoung Yoon is Digital Solution Lead at Gerresheimer. With over 15 years of experience in the healthcare industry, Ms Yoon began her career managing clinical operations at institutions including the Catholic Medical Center and Providence Health & Services. Her journey continued in product marketing and management roles at Philips and Abbott Diagnostics, where she spearheaded product commercialisation and new business development. In her current role, Ms Yoon focuses on expanding Gerresheimer's digital solutions portfolio.

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