

WHY SUCCESS IN DRUG DELIVERY IS NOT JUST ABOUT THE DEVICE

From game changing advances in new diabetes therapies such as Sanofi's inhaled insulin Afrezza to the expiration of blockbuster drug patents such as GSK's Advair – the pulmonary space in pharmaceuticals has never been more dynamic. These current developments present both opportunities and challenges to pharmaceutical innovators and generics manufacturers alike. Here, Mark Tunkel, Partner & Business Development Director, Insight Product Development, explains how companies developing and marketing inhalable pharmaceuticals can explore other strategies to improve patient outcomes over and above what the drug and device can achieve, and thus differentiate their products.

THE NUANCES OF PULMONARY DELIVERY

There has been a lot of activity in the injectable biologics space recently, ranging from new delivery formats such as wearable injectors to developers' ability to drive device differentiation for biosimilars therapies with relative freedom. In contrast, some respiratory combination products such as dry-powder inhalers cannot readily decouple the drug from the device. Generics entering the market are therefore largely confined to replicating current models.

With no difference in drug formulation or device, the challenge that generics manufacturers face is competing for market share against innovator respiratory therapies without a clear way to differentiate themselves. On the other side of the same coin, manufacturers focused on innovating novel

therapies face the challenge of introducing delivery systems that are commensurate with the new therapy. Despite these challenges, clear opportunities exist in both cases to innovate beyond the delivery device alone to drive adherence and effectively compete in this increasingly competitive space.

RESEARCH-FUELLED DIFFERENTIATION

Needs characterisation is critical to making better combination device product development decisions, and uncovering the most meaningful opportunities to drive adherence, adoption, and true differentiation in the market. By leveraging applied ethnography upfront in their innovation pursuits, developers can gain valuable insight to both the universe of key stakeholders for their respiratory device (Figure 1), and their key unmet needs.

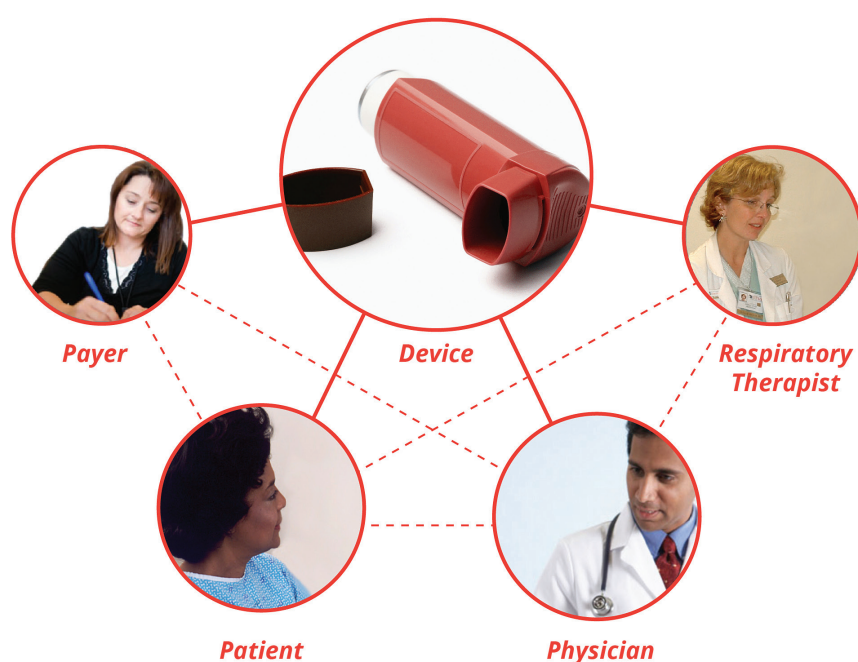


Figure 1: Developers can gain valuable insights about the universe of key stakeholders for their respiratory device.

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Ultimately, this user-based characterisation affords developers the opportunity to synthesise these insights with other inputs from the technology landscape to launch tomorrow's market-dominating therapies.

APPLIED ETHNOGRAPHY

Applied ethnography offers the means to uncover leading opportunities to add value to key device stakeholders while differentiating solutions from the competition. Through a combination of interviews, in-context observation of practices, processes and experiences within their natural settings, and the environment and social contexts that influence them, it helps developers understand the behaviours and motivations of people at the most fundamental level (Figure 2).

By taking this deep dive into user behaviour, pharmaceutical companies afford themselves the opportunity to examine larger marketplace trend assumptions effectively, gain a clear understanding of their key target user needs, characterise those needs in a way that's meaningful, and ultimately define the leading features and benefits of solutions that will be required to make them successful. Even with delivery devices that remain fixed throughout an innovation initiative, leveraging this approach can help developers understand the patient journey in a broader context and use that as a baseline to understand where people having trouble, where are they falling out of adherence, what their drivers and motivations are underlying that, and identify ways to augment users' experience with the device.

DEFINING THE UNIVERSE OF STAKEHOLDERS

In many cases, there is more to designing a positive delivery device experience than focusing on the patient alone. To understand all the implications of the patient experience fully, it's necessary to examine the role of prescribing physician, caregivers that assist with drug delivery, respiratory therapists, nurse trainers and others that influence device selection decisions based on specific disease states, drug formulation and their own ability to administer it. Factoring the roles and leading values of multiple stakeholders in a drug's administration is critical to designing devices that drive adherence.

By examining the entire universe of stakeholders, developers can begin to determine their leading opportunities for innovation.

For example, research might uncover that a nurse practitioner is primarily concerned with the efficacy of new patient on-boarding materials for a respiratory therapy, while a patient may find the most value in the quality of written instructions for use that come with their drug therapy.

UNCOVERING STAKEHOLDER NEEDS

The first step in identifying opportunities to innovate is recognising that you are not developing solutions for a homogeneous population. For drug delivery, you can begin to analyse the vast array of stakeholder needs in two ways across the spectrum of the patient journey: first, by examining the patient journey as discreet steps through the healthcare system; and second, recognising the context of the different life stages of users participating within that journey.

The patient journey helps developers understand the emotional and physical disease management strategies and temporal stages of users, based on the common trajectory of feelings they have toward their disease and therapy. A deep understanding of the emotional drivers, attitudes, and behaviours within each stage of the journey – shifting from denial and resistance to acknowledgement and acceptance – reveals key adoption drivers, adherence and barriers to use, while helping developers determine tangible design guidelines for each patient archetype. As developers, a consciousness of these distinctions is necessary, as – for example – the way you would design for an 80-year-old patient that has



Figure 2: In-field research helps developers understand the behaviours and motivations of people at the most fundamental level.

dictate who the market leader in pulmonary delivery will be tomorrow. A few of the leading opportunities for developers to capitalise on include experience solutions for patients, prescribing physicians, and nurse trainers.

The quantification of adherence will continue to be a primary factor in determining what therapies make it into the prescription plans of healthcare systems all around the world, and what is preferred by prescribers into the future. For this reason, adherence solutions from user training programs, and digitally connected support communities to smart technology that provides motivation and

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been successfully managing their disease for 20 years isn't likely the way you would design for a newly diagnosed 20-year-old.

LEADING INNOVATION OPPORTUNITIES

When the device is a fixed constraint, the leading opportunity for developers to differentiate their offering hinges squarely on the user experience with their device. The ability to drive therapy adherence will ultimately

feedback while highlighting the direct correlation between patient adherence and quality of life are leading opportunities for developers to capitalise on in the immediate term.

NEEDS CHARACTERISATION SUCCESSES

While the proprietary nature of our ongoing projects at Insight prevents us from disclosing our own work, a compelling solution that has recently made its way to market and

OPPORTUNITY MAP

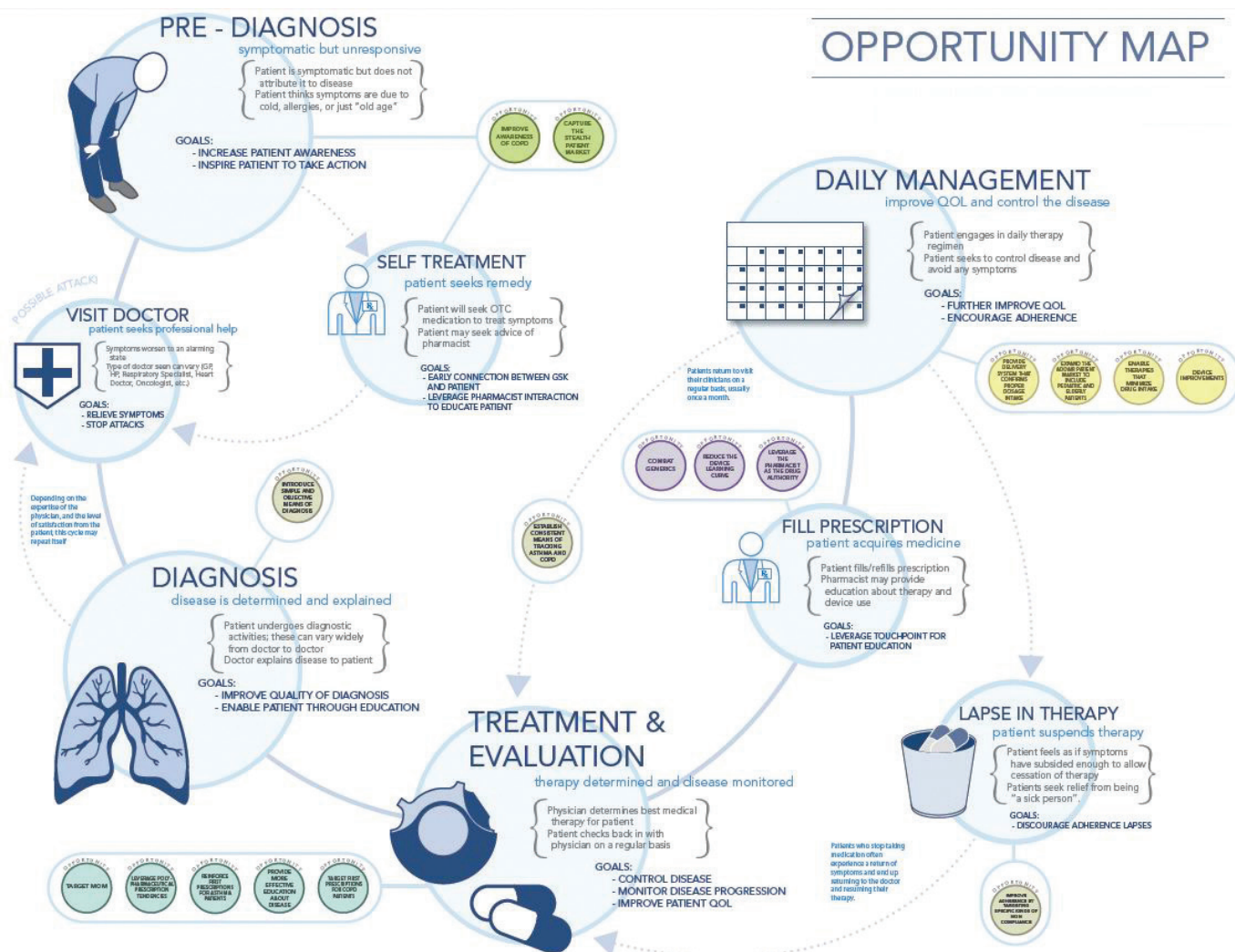


Figure 3: Opportunity map tracking opportunities to achieve greater product differentiation and better patient outcomes, following the patient's journey through the healthcare system and their disease management.

effectively differentiates respiratory delivery devices on user experience alone is the line of respiratory device trainers from consultancy Noble (Orlando, FL, US). Addressing a published study revealing that 93% of inhaler patients are improperly receiving their self-administration medication based on a failure to follow all provided Instructions for Use (IFU), these trainers teach patients proper therapy administration technique to ensure they receive their full dose of medication with every use.

Noble's Executive Vice-President, Craig Baker, explains that because "easy-to-use" is different from "easy-to-learn", patient therapy on-boarding programs are a leading opportunity today in the pulmonary delivery space. Just consider the first time you got behind the wheel of a car, and contrast that against what the experience is like for you today. Unlike healthcare professionals who receive professional training on the safe and effective use of delivery devices, patients often have limited or no experience with such products, which can lead to a number of real challenges from improper technique and user errors to avoid-

ance behaviours. For this reason, Baker says the company developed its specialised training devices for nurse practitioners and patients, ultimately to inspire more confidence among prescribing physicians.

Designed to mimic the actual device and on-board patients through their first 30, 60 and 90 days of therapy, these solutions lead to good habits by teaching patients proper administration through multisensory learning technologies. They include error correction, LED notification, talking audio, and sensors that detect whether the patient has properly primed and inhaled with the correct force, and inhaled at the correct time.

CONCLUSION

Uncovering meaningful user needs, and the immediate challenges that users face in drug therapy administration through applied ethnography is the first step in achieving differentiation in an increasingly competitive marketplace. Figure 3 is an opportunity map developed by Insight Product Development which summarises the

opportunities that arise along the patient's journey through the healthcare system and their specific states of disease management.

By gaining a solid understanding of the complexity of the physical and emotional dynamics of patients, and the preferences and values of all delivery device stakeholders, developers are well positioned to develop user-centric solutions capable of improving patient outcomes and growing market share.

ABOUT THE AUTHOR

Mark Tunkel is a Partner and Director of Business Development at Insight Product Development. With more than 20 years of global business development experience and a deep understanding of the marketplace challenges and trends impacting the pharmaceutical industry, Mark has advised many of the world's leading companies on their product development and innovation strategies with an emphasis on driving realisation and the most favourable business outcomes. Mark holds a BA in Political Science from Indiana University.