PATIENT-CENTRICITY – A WINNING FORMULA

In this article, Justin Schroeder, Senior Executive Director of Global Marketing and Design at PCI Pharma Services, discusses patient-centricity, particularly how it relates to clinical trials in the modern global landscape of the pharmaceutical industry.

There has been considerable discussion about the concept of patient-centricity in the pharmaceutical community. The industry has taken a collective pause in an effort to re-evaluate and rethink longstanding approaches to drug development and commercialisation, with attention being recalibrated on the ultimate goal: making it easier for the patient to reach improved health outcomes. This perspective is underpinned by the recognition that what is best for the patient will lead to beneficial outcomes for all stakeholders, including the pharmaceutical company, the healthcare provider and the supporting community of associated service providers.

There is a famous quote from former US Surgeon General, C. Everett Koop: "Drugs don't work in people who don't take them." It is estimated that less than one third of all prescriptions written are actually filled at the pharmacy by patients. Wide ranging studies have shown medication adherence rates for life-threatening diseases including diabetes, heart disease and oncology can be as low as 30–40%. With the benefit of interventional techniques and developing technologies, adherence rates have been shown to improve, however these programmes have not been broadly adopted within the industry at scale and have not had significant impact decreasing the overall cost of healthcare, nor have they benefitted large populations.

Patients may be non-adherent, some consciously so and some unconsciously, for a variety of reasons. Certainly, we are all admittedly forgetful when it comes to taking our medicine on time or being diligent about timely refills of those prescriptions. Cost can also be a significant factor, whereby patients will consciously stretch out their medication supply or simply go off therapy. In either instance, doing so will hamper the health impact of their prescribed therapy or worse, in a case such as taking a drug holiday while prescribed an anticoagulant, potentially put their life in jeopardy.

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Other considerations may be unwanted side-effects or a lack of understanding about how to take the medication optimally, such as with food or alternatively avoiding food for some period of time, resulting in reduced effectiveness. Fear, or general lack of understanding, can also inhibit the path to improved health by affecting the patient's perception of the medication and their willingness to be compliant.

Likewise, the patient may not physically experience the benefit of the drug, and in some instances may have a negative perception due to the unwanted side-effects. Hypertension is the classic example where a patient may have high blood pressure, but generally not feel the effects of their disease. However, they may experience considerably unpleasant side-effects as a result of their course of treatment. A similar scenario plays out in popular cholesterol-lowering medications. By scale, these two examples are noteworthy, as in the

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US, with a population of more than 300 million people comprised of 75% adults, it is estimated that one in every three adults has hypertension, while 10–20% of adults have high cholesterol. A large-scale patient-centric approach to benefit medication adherence would have significant positive health and economic impacts.

PATIENT-CENTRICITY IN CLINICAL TRIALS

In addition to challenges with patient adherence to medication in clinical trials, sponsors and study organisers are also constantly faced with hurdles such as patient recruitment and patient retention. As the industry is tasked with further expediting drug development and decreasing clinical study duration, the US FDA is increasingly requiring additional studies and additional data to prove long-term safety and comparative effectiveness, including post-market studies once the drug is commercially available in the market. This trend is coupled with an increasing percentage of drugs being brought to market for very specialised disease states and narrow therapeutic indications. This wave of specialised medicines and the ongoing need for treatment-naïve candidates, paired with cost pressures in the R&D sector more broadly, has increased the use of multi-national studies. These complex studies in turn create the requirement for multi-language labelling. This can result in the creation of investigational pharmaceutical product (IMP) study materials that may contain upwards of 16–20 languages on a single label.

Clinical trial professionals are left to balance all of these demands and creatively identify initiatives to keep the focus on the patient. At a surface level, these competing priorities may seem to be in direct conflict. However, when one looks at the situation from a broader perspective, the focus on patient-centricity clearly generates tangible value and outweighs the short-term inefficiencies created by opting for a solution solely on speed or cost.

PATIENT-CENTRICITY IN PACKAGE DESIGN

A practical example of patient-centricity in action can be found in package selection for investigational study. When looking to initiate a clinical study, a sponsor company may be evaluating choosing a bottle or a unit-dose blister in a calendarised format for their clinical study material. Looking simply at the short-term criteria of expediting material for study initiation, where a difference of mere weeks or days can be considerable, the path of selecting a bottle would be a logical solution. It is a cost-effective packaging option, it is relatively "off the shelf" in its availability, it can be hand-filled by a clinical packager with minimal start-up costs, it has an acceptable stability profile for barrier properties and is proven to be child resistant. Conversely, when one evaluates the development of unit-dose adherence packaging, there may be a longer lead time for development and it might be more costly to produce. If looking from a short-term perspective and the immediate pressures of cost and expediting, the choice leaves little room for debate. However, if the sponsor company is taking a holistic approach with a focus on patient-centricity, the broader economics absolutely point to use of the patient-centric package.

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Utilisation of a calendarised unit-dose blister format, or compliance/adherence packaging, offers sponsor companies considerable benefit in both addressing the needs of the patient as well as positively impacting the quality of the data, leading to more efficient studies, and lowering total delivered cost. The use of this style of package allows patients to take medication exactly as prescribed and track their usage, much more easily than with a bulk approach in a bottle format. Physicians can capture vital information on the package, including the specific date to start the therapy and any other pertinent notes for the patient. With the returned package, the patient can physically demonstrate to clinical providers that they have taken the product as prescribed. Furthermore, technologies are available that can provide real-time tracking of patient dosing, allowing for clinical interventions to ensure proper adherence while the study is in progress.

These technologies and principles extend to other delivery forms, including injectables. Increasingly, drug delivery is being driven to allow patients freedom to dose away from the clinical setting, creating new wrinkles and challenges in the way of ensuring proper compliance and adherence, ensuring proper self-administration and realising maximum benefit. The recent scandal with EpiPen raised awareness about how Mylan's technology had substantially changed the market for emergency epinephrine administration and what a distance it had created from its competitors. Amazing new developments are being developed in commercialised prefilled syringes, autoinjectors and pen technologies, as well as new forms such as wearable injectors and infusion pumps. Technologies such as Amgen's Neulasta® (pegfilgrastim) Onpro® demonstrate that drug companies are truly listening to patients and delivering patient-centric solutions to ease the burden of the traditional medical experience. Further developments are being realised in connected health, an exciting new frontier.

The ability to prompt, monitor and even track real-time information is a powerful tool. Likewise, with the advent of Bluetooth and near-field communication (NFC) technologies, packages with integrated technology can capture real-time information about side effects or other vital information as patients take the medication over the course of treatment.

Better adherence leads to healthier patients, and more valuable study data, and may lead to opportunities to change the way studies are administered, such as adaptive trial design. Poor adherence can be rectified and corrected as it happens. Better information gathering can lead to improved patient retention, a significant cost in clinical trial administration and a persistent challenge in study duration. It is estimated that in the industry, clinical studies have, on average, a 30% drop-out rate. With more adherent investigational study patients, health outcomes will be improved and better retention will be realised, translating into reduced total delivered cost, more valuable data generated, and studies executed more efficiently.

PATIENT-CENTRICITY IN CLINICAL SUPPLY CHAIN LOGISTICS

Another area of focus for realising patient-centricity in clinical trials is in the area of study design and administration. Considerable interest is being focused in "direct-to-patient" models, where patients may minimise, or in some instances entirely avoid, the need to come to a hospital or clinic to receive the study drug, as well as to provide critical health feedback. In this scenario patients are engaged by clinical trial or healthcare professionals in a home setting and the study drug is physically delivered to their home by a trained specialist. Clearly this model is not applicable for all studies and disease states, but for certain programmes there can be considerable benefit to the patient and the study. In certain geographies, patients in a traditional clinical study may have to travel significant distances to participate in a study, which can considerably hamper patient recruitment and retention. In a direct-to-patient model, the study effectively comes to them. This model may increase the cost of study administration for the sponsor company. However by executing the study in a more patient-focused approach the sponsor company can realise significant benefit through patient recruitment and retention, again translating into better data, more efficient studies and a faster path to completion.

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PATIENT-CENTRICITY IN A GLOBAL WORLD

One of the significant challenges in taking a patient-centric approach to clinical study execution is the growth in multi-national study execution. Often supplies are designed to pool so that multiple languages are provided, such that materials can be directed to individual countries as needed. This scenario forces sponsor companies either to manage a multitude of language specific supplies, or focus on common supplies where they are forced to condense information due to the shear amount of text being added, often squeezed into a multi-page booklet. Careful consideration must be paid to graphics common to all languages and cultures to ensure patients can clearly comprehend considerably distilled opening instructions, dosing regimens and other key information. Rather than a traditional pooled supply approach, some companies have developed newer strategies for "just-in-time" (JIT) labelling or late-stage customisation logistics, whereby they label study materials according to country-specific requirements at the time of drug dispatch. This can reduce the complexity of a scenario where they would be trying to accommodate 16 different languages on the same label in a multi-page booklet approach. This JIT strategy may decentralise supplies, but may bring other benefits in meeting the language and cultural needs of patients in their geography, as well as those of the study administration.

PATIENT FOCUS YIELDS POWERFUL RESULTS

The industry is in the infancy of its patient-centricity journey, but it is clear that, with a focus on the patient, many tangible benefits are realised by drug companies in their development and commercialisation of life-saving medicines. Encouraging relationships are being formed with patient advocacy groups, providing valuable insights for drug development and clinical trial administration, resulting in considerable breakthroughs being brought to market. With so many significant advances over the past decade, it is exciting to see where this patient-focused journey will lead, as new patient breakthroughs are happening every day.

ABOUT THE COMPANY

The global healthcare industry trusts PCI for drug development solutions that increase their products' speed to market and opportunities for commercial success. PCI has proven experience that comes with more than 50 successful product launches a year and over five decades in the healthcare business. Leading technology and continued investment enable the company to address global development needs throughout the product lifecycle — from Phase I clinical trials through commercialisation and ongoing supply.

ABOUT THE AUTHOR

Justin Schroeder is Senior Executive Director of Global Marketing and Design at PCI Pharma Services, responsible for global marketing, creative package design and new account development, with a focus on the development and commercialisation of new products. Mr Schroeder has over 20 years' experience in outsourced pharma services in various roles, including engineering, project management, marketing and development. He holds a Bachelor of Science from the School of Packaging at Michigan State University, US, and an MBA in marketing from Northern Illinois University, US. Mr Schroeder is a certified Packaging Professional from the Institute of Packaging Professionals, US, and is Vice-Chairman of the US Healthcare Compliance Packaging Council.