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Generating, managing and using patient insights

'Insights deeply identify why individuals are doing what they are doing and can enable prediction of their future behaviour and needs.[1]'

Patient insight is fundamental to the ability of a pharmaceutical company to add value to the healthcare ecosystem within which it operates. While this statement is generally accepted, more specific definitions of patient insight and its value are often helpful.

As pharmaceutical companies explore opportunities to improve the way that they incorporate patient insights into the development and commercialisation of their medicines, several key aspects must be considered. As well as evaluating the various channels through which they can interact with patients in a compliant way, pharmaceutical companies should also critically assess their internal capabilities to generate and manage patient insights.

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[1] *Smith and Raspin, Creating Market Insight (Chichester UK, Wiley, 2008).*

The value of patient insights

At recent Kinapse discussion fora on 'patient centred pharma', executives and patient group representatives agreed that there is a current need, as well as an opportunity, to radically improve the way that patient insights are incorporated into the development and commercialisation of medicines. While the opportunity is driven by increased public availability of information and improved connectivity, the need is not always adequately defined or articulated within a company.

The benefits of capturing patient insight may differ depending on the stage in the lifecycle of a medicine, the therapy area, and the geographic region. For example, patient input to a development programme could result in improved likelihood of reimbursement on the basis of differentiation through inclusion of less traditional end points in trials (see case study 1). With many chronic diseases, patient adherence is an issue, and a deeper understanding and segmentation of the patient population will identify perceptual barriers to adherence as well as practical barriers. Support and solutions can then be tailored accordingly (see case study 2).

Practical barriers to success

Many organisations are exploring opportunities to improve their capabilities in this area, but there is often a need to specifically:

1. Ensure that processes and other elements of the operating model can support effective generation and management of patient insights
2. Understand the role of various data generating channels, as well as data analysis technologies
3. Overcome perceived as well as real barriers to direct interaction with patients, and to understand and mitigate any risks.

This paper addresses these challenges to the effective generation, management and use of patient insights in a pharmaceutical company.

> *From our standpoint at ICAN, if the biopharmaceutical industry integrates the reliable, seasoned patient voice, from every aspect of protocol design to conveying actual clinical trial results to the patient community, then not only will we, as a global clinical trials community, have better patient recruitment and retention but we will be able to bend the cost curve down for the entire pipeline.*
>
> **Marcia K. Horn, JD President and CEO**
> **International Cancer Advocacy Network (ICAN)**

Case Study 1

Improving likelihood of reimbursement

It is well known that fatigue is a concern for patients suffering from Systematic Lupus Erythematosus. However, it may not be clear how important this aspect of the disease is to people living with the disease. Furthermore, fatigue is not a major end point in controlled studies because it is a patient reported outcome and not easily quantifiable. It is therefore difficult to include data on fatigue as part of the reimbursable file.

Real Life Sciences has developed technology which reliably surveys patient conversation online. This provides a mechanism to gauge what patients feel is important and how they perceive their outcomes. As shown in figure 1, 7.3% of the Lupus population surveyed reported fatigue in their postings. Of the population taking Product X 56% reported improvement in fatigue and only 12% reported no improvement at all. Could the reimbursable file for Product X have been strengthened by incorporating this type of patient insight?

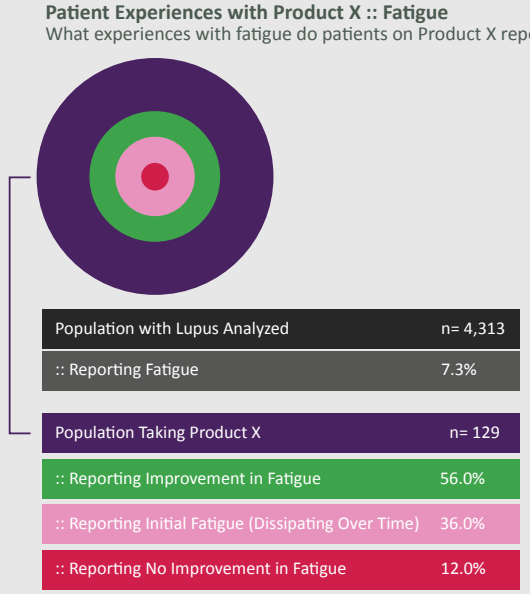

Figure 1: Analysis of SLE patients and experiences with Product X

Evaluating the operating model

While the most obvious aspects of the operating model to consider are the processes and responsibilities, a holistic view surfaces more subtle elements to consider. Figure 2 provides a synopsis of key areas.

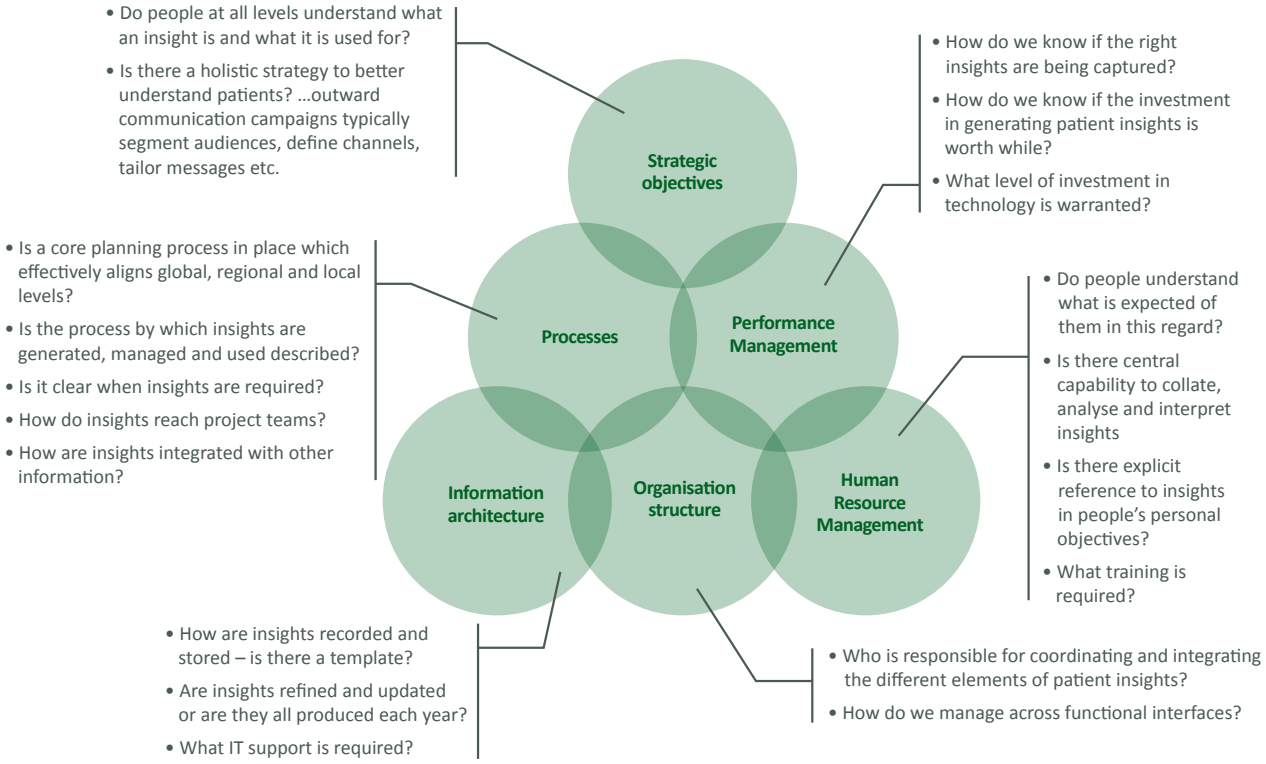

Figure 2: Key elements of the operating model to consider

Processes for information management

From a process perspective, the ability of an organisation to generate, manage and systematically incorporate insights must be built off the back of a robust planning process which aligns global, regional and local activities, and is driven by overarching objectives. In our experience the planning process often works well in the dissemination of objectives and tactics and allows tracking of performance in executing the plans and in meeting the needs of the development plan or the market. The processes are often less effective in managing inflow of information from countries, and tracking performance in meeting the needs of the patient. Where insights are effectively generated, they are rarely codified and stored in a way that enables their use by multiple internal project teams.

Roles and responsibilities

While an individual is clearly responsible and holds budget for the development and execution of a plan, there is less clarity on responsibility for patient insights. Due to the potential complexity in collating information from disparate sources, integrating it with internal information, and ultimately analysing and packaging it for multiple internal audiences, we would recommend a dedicated role responsible for insights in each particular therapy area. This role must remain in the therapy area and would potentially report to the therapy area lead or business unit head. Creating a separate group would remove the onus from the day to day working of the team. A clear point of contact within each therapy area would also make cross functional communication simpler.

Given the nature of the task, the requirements of the role would be as much facilitation and coordination as direction and execution. In terms of capabilities, a medical background would seem logical, but if a role were created, consider the effectiveness of a person with experience in Amazon, Apple or Procter & Gamble rather than a person with a traditional Medical Affairs or Medical R&D background; a combination of the two would be ideal.

Understanding the potential and the role of technology

Patient insight' is a nebulous term and is often used loosely along with terms such as 'big data'. With both terms, there is also much discussion on the need to search unstructured data and free text on the internet. Patient insight will indeed be supported by analysis of free text on blogs which describes aspects such as preferences and challenges, but quantitative information on issues such as adherence (e.g. proteus® technology) will be equally important. It largely depends on the questions that need to be answered, recognising that several iterations may be required to suitably refine those questions.

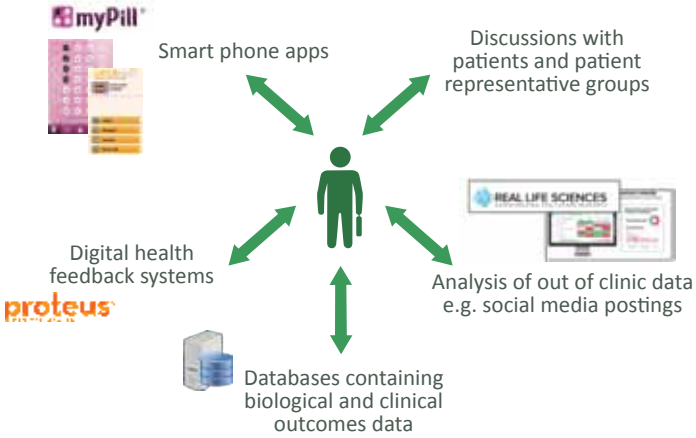

Figure 3: Sources of patient insight

Organisations must invest time defining what information is required and what channels are available before defining the technology requirements. A framework such as SIPOC will help to segment audiences, and then identify how best to identify and approach different segments through different channels; for example, where adherence is the issue, patients with low adherence due to concerns will be identified and approached through different channels to those with unintentional non-adherence due to practical barriers. Furthermore, the optimal combination of channels will vary by disease area e.g. we would expect a rare paediatric disease to have a more active online community than that for cardiovascular disease.

In order to maximise the value of patient insights it is also important to integrate that input with other information to which the organisation has access e.g. study data, input from external scientific experts etc. This paradigm shift from classic data management to an information management focus requires a different dimension of technology.

The ultimate challenge will then be to use technology effectively to translate large quantities of structured and unstructured data and information into a standardised format which generates hypotheses, or answers specific questions within the organisation. Given the different types of information, and the different contexts and standards in which it is collected, human intelligence must complement the technology and cannot be excluded from this process. In some organisations resources are dedicated to this task, but it can also be outsourced as a specific service.

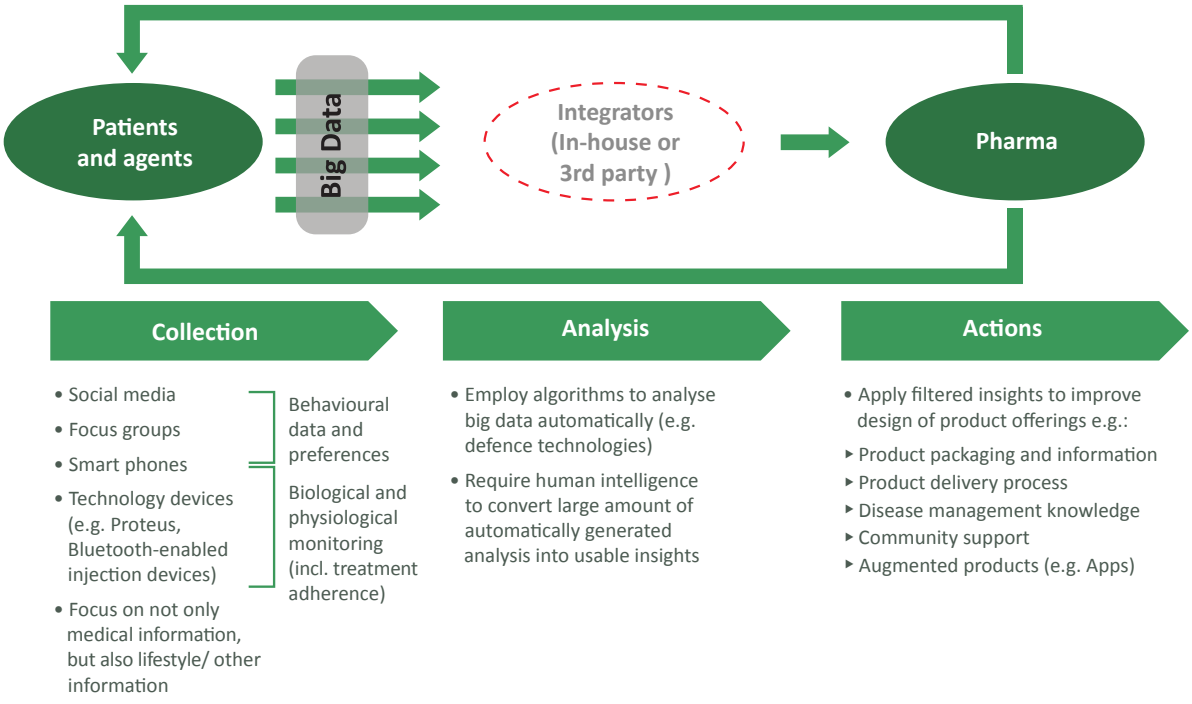

Figure 4: Capturing product experience of patients and their agents

[2] SIPOC is an abbreviation for Suppliers, Inputs, Processes, Outputs and Customers, and is a framework used to define a process before analysing, refining and improving it.

Understanding barriers and risks

While direct interaction with patients does require careful navigation, there appear to be a number of unfounded assumptions. As with all non-promotional activities, interactions must be handled carefully, but in most countries there is no legal or regulatory guideline which prevents pharmaceutical companies interacting with patients in a non-promotional way. The barriers are often within a pharmaceutical company, and there is no reason not to include patients or patient group representatives on advisory boards for example. The more important area to explore is the potential ripple effect on social media when patients subsequently discuss meetings online. Judgement and balance are required in interactions, and a risk management plan is essential.

Where companies are monitoring patient interaction online there is often anxiety about the responsibility to recognise a reportable adverse event on social media. There are clear guidelines and criteria in this regard, and there is no reason not to have a documented plan to invoke the potential safety report.

In summary, there are risks which cannot be ignored in the collection of insights from patients, but risk analysis and management is no different to that in other parts of a pharmaceutical company. Patient group representatives have expressed an appetite for further interaction, and Kinapse is working with patient representatives and regulatory agencies to identify and address the areas of ambiguity.

Case Study 2

Improving patient adherence

A 2003 WHO study estimated 30-50% non-adherence across long-term conditions. This negatively impacts patients, healthcare systems and pharmaceutical companies, and must be addressed through innovative collaborations between the parties involved. In simple terms, improved adherence will positively impact the health of the patient, reduce cost for the healthcare system, and increase sales for the manufacturer.

As shown in figure 3, a number of channels are available through which information on patient adherence can be gained. Proteus and similar technologies can provide information on adherence, but different channels must be used to understand adherence in detail. Ultimately, a combination of the channels shown in figure 3 will enable a team to better understand the reasons for non-adherence and to identify the various segments of the non-adherent patient population (figure 5). Only then can targeted solutions be put in place to address the practical or perceptual barriers e.g. reminders through additional safety messaging, additional web based resources or smart phone apps (notwithstanding the data privacy issues related to the latter).

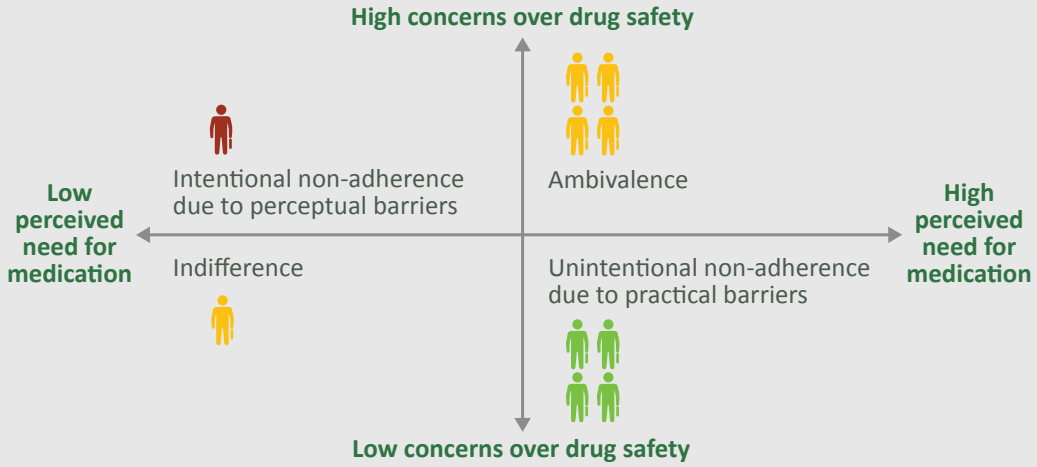

Figure 5: Understanding non-adherence

[3] *World Health Organization (WHO). (2003). Adherence to Long-term Therapies: Evidence for Action*
[4] *Horne, R., Parham, R., Driscoll, R. & Robinson A. Patients' attitudes to medicines and adherence to maintenance treatment in inflammatory bowel disease. Inflammatory Bowel Diseases, 2008.*

Conclusion

Many pharmaceutical companies are rightly considering opportunities to radically improve the generation, management and effective incorporation of patient insights into the development and commercialisation of their medicines. However, several key aspects must be considered before investing further in this area.

A key investment decision is around technology, and management must consider that in the context of their questions and the patient segments from which they are likely to want answers.

Kinapse continues to work with clients to address the areas discussed in this paper, and we have found that a pilot approach with a specific product or brand team more valuable than a companywide initiative in the first instance. Where a pilot project is successfully completed, further iteration and refinement can then expand and embed effective ways of working in the organisation. We believe that optimising the generation and management of patient insights within a pharmaceutical company can deliver significant benefits to both the company and the patients that it serves.

About Kinapse

Kinapse provides consulting and outsourcing services to life sciences organisations. Our mission statement is: 'Collaborating with our clients to innovate for exceptional results'. Kinapse clients include many of the world's leading pharmaceutical, biotechnology, medical device and specialty pharmaceutical companies, government organisations and life sciences service providers. Our key advantages are:

- Focus on the life sciences industries
- Deep industry experience and technical acumen
- History of successful project delivery

During 2013 Kinapse facilitated focused discussion groups which addressed 'patient centred pharma' and specifically what is required to move the concept forward at an operational level. Forum attendees included patient representatives, pharmaceutical company executives, and technology providers.

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