Doctors hold the key to understanding patient outcomes

Listening to the patient voice has become critical for pharma in a world where real-world outcomes are as important as clinical data. In the age of digital and social media, numerous new channels are opening up to collect such healthcare 'big data' and enable rapid analysis of the patient response to new medicines. However, the doctor has always been closest to the patient and still has a vital role to play in such research, if enabled to do so.

The pharma industry has recently become increasingly vocal about being more patient-centric. This is driven not just by a genuine desire to improve its relationship and reputation with patients, but also by the recognition that it is essential to understand the real-world impact of new medicines, with the patient voice playing a key role in providing such feedback.

But what is the best way to listen?

In today's digital world, online patient communities and the early promises of integrated electronic medical records are seen as significant opportunities for collecting 'big data' on how disease is being managed beyond the clinic. However, some techniques for patient research have been around far longer – and the doctor is at the heart of them.

Patient record studies have been conducted for many years, with the doctor playing the role of researcher. Here, the doctor provides data on a number of real patients from their own practice, defined by predetermined characteristics, either by studying the actual medical records, by recall or through direct engagement with the patient. Whilst this research technique may be more traditional, it has also adapted with time and still has a unique part to play in helping the doctor unlock the valuable patient voice.

For those less familiar with this approach, research projects conducted by this methodology are typically defined in a number of ways, as outlined in figure 1.

Broadly speaking, this technique can be used for interventional studies, rather like a clinical trial, whereby subjects who are given a particular medical treatment are compared with a control group. However, when it comes

Figure 1: An overview of the types of patient record studies and their outputs.

Study aspect	Variations
Time period	• **Retrospective:** Historic patient records are used to complete the charts in line with the study criteria. • **Prospective:** Charts are completed on an ongoing basis as new patients are seen that meet the study criteria.
Collection methodology	• **Recall:** Doctors complete charts based on their recall of specific patients. • **Look up:** Actual patient records are interrogated to complete the charts. • **Direct:** Direct feedback is obtained from individual patients (anonymised).
Outputs	• **Patient charts:** Patient chart data only, including patient demographics. • **Patient charts + survey:** As above, but also including collated survey responses.

to assessing real-world data the value of understanding patient records is derived through non-interventional studies – observing patient outcomes for defined populations.

Here, patient record studies are most commonly used for two areas of research:

1. Post-marketing surveillance studies (PMS): For post-marketing surveillance studies, data is collected on patients who are being treated in line with current therapeutic strategy (i.e. there is no 'trial' protocol), with diagnosis and monitoring as per standard medical practice. The real-world data collected often reveals interesting aspects of treatment efficacy, prognosis, quality of life and adverse events that may not be picked up within a clinical trial.

2. Post-authorization safety studies (PASS): Essentially, a subgroup analysis of a post-marketing surveillance study, here the focus is on accurately understanding adverse event frequency in the real world (and identifying any previously unknown adverse events). Again, the results may be markedly different to those observed in a tightly defined clinical trial population with restrictions on associated comorbidities.

There are numerous other types of non-interventional studies (cohort studies, case-control studies, register studies etc.) but the common theme is the rich data they provide on 'real' patient populations that have not been carefully screened for clinical trials. In other words, exactly the real patients that government bodies are also looking at when assessing whether medicines are cost-effective.
It is a myth that patient record studies are difficult or too challenging, provided that doctors are properly trained. On the other hand, interactions with payers are frequently challenging in the absence of appropriate real-world data!

The role of the doctor in collecting patient data

A number of other routes exist for collecting real-world patient information that potentially circumvent the doctor, including online communities, patient advisory boards and, of course, the emerging field of electronic medical records. The doctor does, however, bring a vital additional dimension when utilised properly.

In reality, no single technique is perfect and the appropriate research route at any time depends on a number of factors including:

- Required patient demographics
- Output data – qualitative or quantitative
- Quality of data
- Volume of data
- Cost
- Speed of delivery

One of the key aspects here is the type of output data desired – volume, quality and whether it is qualitative or quantitative. Instinctively, when you ask patients directly for feedback on particular treatments, the information they are most comfortable providing is qualitative. Patients want to talk about how a particular drug makes them feel, how it has improved (or not) the quality of their life, what concerns they have over taking it and what unmet needs remain, for example.

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These are extremely valuable insights, but are very different analyses to understanding what proportion of patients experience a particular side effect, how many patients within a particular disease area switched to a new medicine because the one they were on is not working or pinpointing exactly how prevalent particular comorbidities are within a certain patient pool. Cumulative patient responses can, of course, provide estimates of these, but the more historic the analysis the more dependent you are on patient recall, which reduces data quality.

When reviewing patient records, it is 'real' data that is being evaluated – less about opinions and attitudes and more about real prescribing behaviour and the patient's actual response to particular medications. In addition, valuable information around patient demographics, prescribing history, laboratory information, diagnostic information and previous conditions / current comorbidities is all at the doctors' fingertips. Involving the doctor in analysing these medical records is therefore likely to yield a more robust response to these critical quantitative questions, which are also the ones most often asked by payers seeking to understand the value of a new medicine. Furthermore, the doctor can, if required, supplement this recorded information with direct patient feedback to provide a mix of quantitative and qualitative insights.

Quality of data is always another hot topic. The ability to quickly collect enormous amounts of data cannot be at the expense of accuracy – big data cannot lead to any meaningful 'big solutions' unless it properly represents the real-world situation. This is where the doctor can also play a role as 'quality referee'.

Poor data quality can be driven by systematic errors such as improper recall of facts and inaccurate recording of

information. However, it can also be driven by selection bias, where the samples being assessed are not properly representative of the broader population. Any form of research is prone to such bias and it is important to consider whether the collection methodology is having an impact on the results. A good example would be conducting an online survey to ask patients if they like to receive medical information via online channels, where respondents are more likely to be digital advocates because of the collection route.

With the right support, the doctor can ensure research bias is reduced and also maintain a watchful eye for irregularities that might otherwise be missed. Of course, there is always the potential issue of misreporting data, but this is true for every research route and a key factor here is the relationship with the doctor.

Finally, when it comes to collecting appropriate volumes of data in a time- and cost-effective manner the doctor can effectively become the 'project manager', provided they are given sufficient training, support and motivation. In addition, given the understanding doctors have of their patient populations, they can often provide a very accurate guide on what volume of data is feasible within what time frame.

Supporting the doctor as a real-world patient researcher

Whilst there are tangible benefits in working with doctors to procure valuable patient information, it is important to remember that actually looking after their patients is the number one job for them. It should also be recognised that producing patient record charts can be quite daunting, lengthy or repetitive for doctors, so not all of them will have the time, expertise or inclination to get involved in such research.

It is therefore important to build strong relationships with doctors, if you are to work collaboratively with them in unlocking the value of their patient data. There are three key aspects to this.

1. Providing training and support

The more patient record studies doctors have done then the more comfortable they are in conducting these projects. It is important to help train them in the research techniques and then maintain strong links with those doctors who have developed their expertise, especially in niche therapeutic areas or emerging markets, where the local techniques may differ. For example, in a number of the emerging Asian markets doctors prefer to conduct such research face-to-face.

Such training is also important in planning the feasibility of patient record studies, allowing doctors to accurately assess at the start whether they can provide the required information and how long it will take to deliver. In addition, even with the most rigorous training and prior experience, doctors are always going to come across challenges they have not previously encountered. Here, having someone at the end of the phone via a manned helpdesk is important to avoid doctors dropping out of studies.

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The training and support provided also has to adapt as time goes on to reflect the way in which doctors collect this information. Although electronic medical records have only recently started to emerge as potential centralised data repositories, doctors have been shifting to storing local patient records digitally for some time, with a minority now stored in paper format (see figure 2).

Even with modern techniques and quicker access to online information, more complex studies can see doctors taking 45' per chart, where good training and support is vital to successful completion.

2. Ensuring accuracy by reducing bias

There are two ways to reducing sample bias when collecting patient data via doctors. The first is to structure the methodology in such a way that minimises the risk of bias. For example, asking the doctor to provide information on five patients may lead to them just picking the first five patients out of their files, which could skew the outputs, depending on their filing system.

Instead, randomisation techniques can be used that might, for example, randomly propose the first letter of the surname for each patient to study. The same approach can be taken with all kinds of other factors, such as age, gender, comorbidities etc. As information collection moves online, digital randomisation techniques have helped to make this process quicker and easier.

The second aspect is ensuring that the doctor understands what is behind the randomisation and why it is important. Applying such techniques to reduce bias normally leads to an inherently more drawn-out process for the doctor, so they need to appreciate the benefit upfront.

3. Incentivising appropriately

Doctors like to be involved in patient record studies when they feel it is a worthwhile use of their time and that it can indirectly benefit their patients, but their time is valuable and so it is always a trade-off versus sitting in front of their patients helping them directly.

Incentivising doctors to be involved therefore comes down to providing the right honoraria and flexibility around how much time is required from them. For example, some doctors may only have time to provide a couple of patient charts, whereas others may be happy to provide ten or more, so setting a minimum and maximum volume, with appropriately scaled honoraria per chart is better than setting a fixed amount. Some doctors may also like to provide charts sporadically, taking time off in between providing each chart.

Ultimately, in any given study the important factor is ensuring that the right volume of data can be obtained overall from a panel of doctors, rather than being overly reliant on a small number of doctors, and the incentives offered must reflect this.

Allowing doctors to be the conduit between patients and pharma

There are a multitude of research routes emerging for assessing the impact of medicines on real patient populations and they all have those with the best view of these outcomes – the patients – at their core. Patients are well placed to provide feedback on how well a particular treatment is addressing their condition and any adverse effects it may be having on their life.

In a complementary way, doctors bring a useful qualified perspective on the impact a particular treatment is having on a patient and the medical training to properly interpret other critical demographic and historical factors within the same context.

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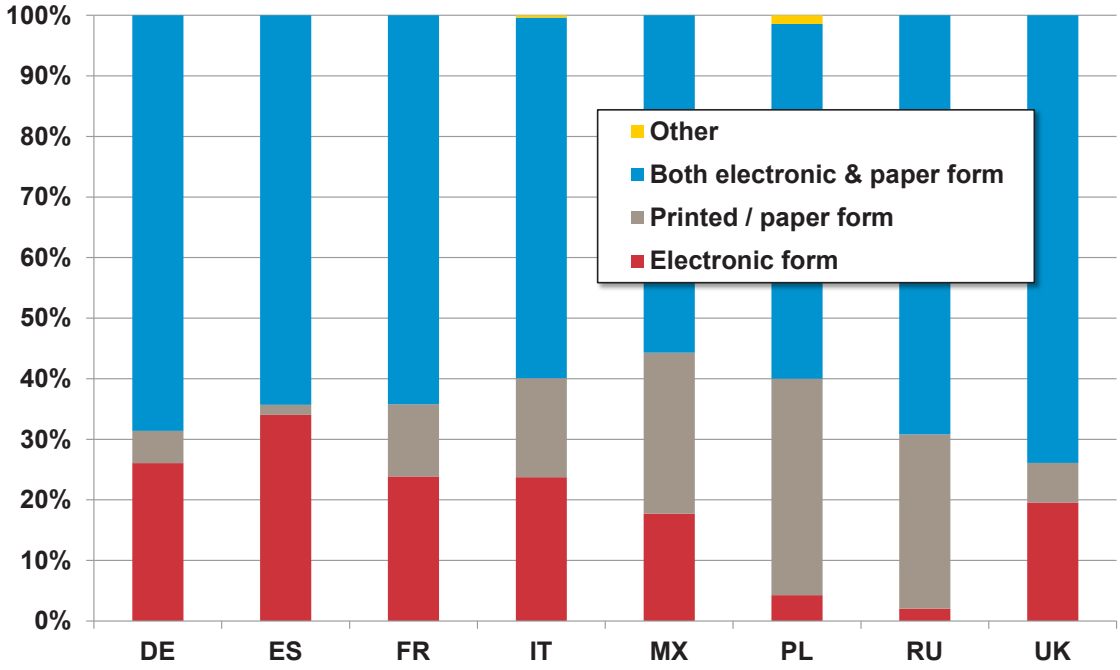
As such, the information provided by patient record studies, coordinated by experienced doctors, can address all kinds of business critical questions for pharma in a highly focussed way. Perhaps more importantly it can produce useful insight that might not even be anticipated when planning the research.

For example, a typical study might collect the following information:

- Several hundred patient charts across multiple geographies.
- Additional supportive anonymised qualitative patient feedback for a 360 degree view.

Figure 2: Proportion of patient information stored online by major markets in 2012.



- Key demographic information such as gender, age, disease specifics, comorbidities, general state of health (BMI, smoker vs. non-smoker etc.).
- Medical interventions and history, including current medications and full prescribing history.
- Historic records of any clinical improvement and adverse events.

Whilst pharma might enter into such research looking to obtain a view on the real-world efficacy of its new medicine, it might start to uncover subgroups of patients that exhibit amplified response to treatment, variable patterns of adverse events or even crucial information around adherence challenges. Even though the research is non-interventional, the support of doctors in providing both quantitative and qualitative information could then guide further post-approval clinical studies that better demonstrate the value of the medicine.

In today's connected world, engaging with doctors and patients is easy. Utilising the right techniques to obtain accurate, informative data that guides development and commercialisation decisions that will benefit patients is much harder. This requires the support of educated and informed doctors who can work with their patients to provide the right research outputs.

Clinical data that meets the needs of regulators remains the primary aim for introducing new medicines to market. But obtaining an accurate view of the impact medicines have for patients beyond the clinic is now essential for the pharma industry. Real-world, accurate outcomes data is now the currency of success for the industry – who better to help provide this than the doctors who sit in front of these real patients every day?

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