



The value of patient reported outcomes

Su Smith, Director of Origins, shares her thoughts on the evolution of patient reported outcomes and the strategic advantages of gaining a deeper understanding of the patient's own perspective.

The journey towards true patient centricity

The patient voice is now at the centre of drug development. As with any journey, there has been more than one route to the destination. The expression 'no decision about me, without me' came from the idea that for patient voice inclusion, information needed to be shared in ways that patients will understand, so they could help make those informed decisions. More recently the major pharmaceutical regulatory bodies have strengthened their positioning in demanding patient focused drug development. Patients need to be involved at every stage, not just as subjects in a clinical trial, but as the experts of their own condition. In the same way that the doctors are the intellectual and medical experts on their condition, the patient is the one with the lived experience. So, the regulatory bodies are now requiring evidence of the collaboration with patients in drug development. This applies to both their input into the design of the clinical trials as well as their input into what the practicalities of that condition mean on a more qualitative level.

Today, new products that are currently in clinical development are in a different space, in that they are required to be patient centric. There is still a lot of education required of the pharmaceutical industry as to what it means to be truly patient centric.

Understanding the patient's objective

The drivers for drug development have long been focused on what doctors believe is a good treatment and what will make a clinical difference to patients, while being cost effective. But patients may have their own objectives. With a condition like psoriasis, for example, a physician's clinical objectives don't always consider the intense itch and burn that the condition brings – experiences that patients have reported as the most important aspects to them. This is where taking a patient-centric approach can add value. What are the benefits of the drug to the patient that go beyond what the clinician or the payer is trying to achieve from a cost perspective?

Where the real value comes

Patient reported outcomes are formal measures that, as the name suggests, are reported by the patient without interpretation by a clinician. We need to know what the patient said

or felt, and the data they entered, we want the uncoloured version. Patient reported outcomes play a key role of the inclusion of patient voice in patient-focused drug development.

How patient data is captured

Patient reported outcomes need to be quantifiable so that there is no ambiguity – rating scales and event counts are good example of these. At Origins we have done many qualitative insights projects that explore the patient voice, but where possible we included patient reported outcomes as an element of the project to give deeper meaning and context to the insights. Examples have included pain scales and seizure counts.

There are some challenges associated with patient reported outcomes. These are mainly linked to the understanding of how to complete the information by the patient and the additional burden capturing this data may add to a patient's life. Sometimes patient reported outcomes and patient voice get interchanged and mixed up. There is a place for both, but the purity of patient reported outcomes as data shouldn't be confused with the qualitative depth of information that you can get from the inclusion of patient voice and opinion.

The strategic advantages

At Origins we are clear on the distinction between patient voice and reported outcomes. But there's a strategic element here too. As well as the importance of the data to the patient, there's the insights and the solutions it can offer, and how that can then give pharmaceutical companies better outcomes in terms of getting their drugs to market. Modern, relevant patient reported outcomes will put them in a strong position for patient focused drug development. We also believe that it's a part of end-to-end patient strategy. From the moment that you make the decision, that, "Yes, we are going to develop a drug in this therapy area", that is the moment you should employ your patient-centric strategy.