Will real-world evidence make an impact in 2014?

Collecting real-world data will present a huge challenge for pharmaceutical companies developing a new medicine, so they need to start planning for it early in development, says Thomas Lönngren, strategic advisor, NDA Group

2013 HAD MANY hot topics on the agenda, ranging from monoclonal biosimilars to transparency of clinical data. The question now is will we face new issues this year, or will we have the opportunity to focus on the many unresolved topics that still require further debate and mature deliberation, before we can tick the box and declare 'job done'?

One item I believe will be prominent on the 2014 agenda is the debate around real-world evidence.

The key concern is that clinical studies currently performed for regulatory approval do not provide the information necessary to show how the medicines will perform in the real world. With the 2012 introduction of EU pharmacovigilance legislation, companies are now obliged to follow up new medicines once they are made available to patients, with increased emphasis on post-authorisation safety and efficacy.

From the payer's point-of-view this is a welcome change. They need companies to shift the focus away from assessing cost-effectiveness and added benefit at the time of approval, to monitoring the performance of the commercialised medicine once on the market.

Collectively, this is bringing about an increased demand to generate data from the real-world use of medicines. But although this may seem straightforward to achieve, the reality is quite different; it requires stakeholders with very different perspectives to come together.

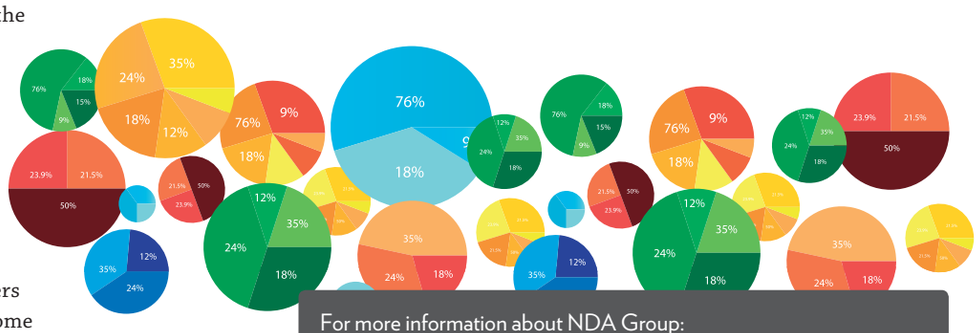
Additionally, if regulators and multiple payers' bodies are demanding these follow-up studies, we need a common approach to their design and how they're performed. Today, regulators and payers ask for different data and outcomes, but there is the potential to coordinate studies to save time and cost.

Structure is just one issue, however. We need to plan where to perform these studies, how to get access to the data when healthcare systems are under financial pressure, and how to interpret the data as the quality varies.

Another debate surrounds the need for interventional studies versus the value of observational studies. For a pharmaceutical company developing a new medicine this will be a huge challenge.

Yet one thing is clear: companies need to start planning early in development to generate the necessary evidence as soon as the medicine is launched. The regulatory process leading up to filing a marketing application, including a comprehensive risk management plan, is just one milestone. At this stage the company needs to satisfy regulators and payers by having a clear strategy on how to generate real-world evidence once launched, which in turn will be linked to the risk management plan.

In the process of generating real-world data, we should not forget that studies alone do not improve the performance of a medicine in a health system. Data will only inform us whether the medicine is performing properly, as predicted or not. So, before embarking on real-world studies, companies also need strategies to improve the performance of medicines in clinical practice, further emphasising the importance of risk minimisation. ◘



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