PART IV:
WHERE DOES REAL WORLD EVIDENCE FIT WITHIN THE PRODUCT LIFECYCLE?

Real World Evidence (RWE) is clinical data which has been collected outside of a conventional randomised controlled trial. For the RWE Series, we set out to answer the essential questions and explore the key issues surrounding RWE.

In the previous articles we have outlined the importance of RWE, how the data can be collected, and its analysis. Here in the final part, we focus on when and where RWE can be used.

This is the fourth and final part of the series available at svmpharma.com
When should you use Real World Evidence (RWE) and how can you make it fit into your projects and timelines? This is a key question and understanding this will enable you to maximise its potential and use resources effectively. A good starting point and framework for this discussion is the product lifecycle. This was a term coined in the mid-1960s and since then has become increasingly relevant to pharmaceutical industry. It has been widely adopted and offers a base from which to explore how this complex industry works.¹

There are several variations of the product lifecycle, here we will split the cycle into the following four phases: development, launch, growth and mature. In the chart below you can see the importance of RWE along the breadth of the pharmaceutical product life cycle and the various opportunities available to collect data in order to reinforce the value of your product.

REAL WORLD EVIDENCE: BRIDGING THE GAPS IN DATA THROUGHOUT THE PRODUCT LIFECYCLE

**DEVELOPMENT PHASE**

The product lifecycle begins with the inception of an idea and the desire to create a molecule that can treat a disease. *De novo* drug discovery and development has been estimated to take 10-17 years and has high attrition rates (10% probability of success from concept to launch).² This includes target discovery, screening, lead optimisation, pharmacodynamics and toxicology testing, phase I to phase III clinical trials and finally registration.³ Drug discovery and development is a dynamic and innovative area, for example, the recent explosion of genetic testing and genotyping has opened up new data sets to support the development of targeted therapies.⁴ One such programme is 100,000 Genomes Project which aims to accelerate the development of new treatments in partnership with the pharmaceutical industry.⁵

Due to the tremendous investment in time and resources required, additional data to support decision-making is crucial to successful drug discovery and development. Both large and small RWE datasets can be used to identify unmet needs and the disease burden, and help verify the potential of a programme in the early stages.⁶ Implementing RWE at this
early stage may help alleviate the high risk of drug development.

Big Data and healthcare analytics is becoming increasingly important within the clinical trial setting to support patient recruitment, and for trial design and implementation. Patient demographics and population characteristics are key to ensuring a representative sample for a clinical trial. Custom RWE data collection programmes can be run alongside a Phase III clinical trial to answer newly arisen questions and fill gaps in knowledge efficiently and quickly.

The role of RWE pre-launch has been recognised and promoted with the IMI GetReal Initiative launched in October 2013. This pan-European consortium includes the EMA, HTA bodies, academia, patient organisations and a number of leading pharmaceutical companies and seeks to construct a ‘uniform framework for the use of RWE’.7

**LAUNCH PHASE**

The launch of a product is best described as a phase, rather than a single event. It is important to understand the existing standard of care and the current state of the market to shape marketing strategy pre-launch. RWE data collection programmes can help build relationships with prescribers and centres which proves beneficial during this period. These advocates can encourage use of the product and influence the behaviour of their peers, giving the drug a head start. Furthermore, real-time analysis provides instant insights into their collected data and this can be compared to aggregated data from other centres. RWE data allows accurate calculation of costs which is important to understand the budget impact for payors and hence set pricing strategies, set patient access schemes and negotiate deals accordingly.8,9

**GROWTH PHASE**

The growth phase involves building market share and then maintaining and defending the gains. This is where RWE shines, offering a multitude of ways to enhance competitiveness and show the value of a drug during the vital period after launch. Data collected at this time can assuage doubts regarding real life efficacy and outcomes of a new product, and may be part of an arrangement with the payors. Many decision-makers await national funding body (e.g. NICE, SMC) approval and recommendations before adopting a new product, and RWE data is increasingly and successfully being used to support submissions.10,11

As this phase progresses, RWE data collection of the new drug’s clinical outcomes and prescribing patterns can help direct marketing strategy and ensure these resources are allocated effectively. Discovering the reasons for poor adherence and ensuring a positive patient experience can be key to improving market share and designing holistic value-added services. RWE data collection programmes have the capacity and flexibility to collect qualitative data and do justice to patients’ thoughts and ideas. As we head towards maturity of the product, it is possible to begin to look at medium and long-term clinical outcomes via analysis of large datasets or smaller data collection programmes. This longitudinal data of patient cohorts would have been difficult to collection via traditional trials and can be used to evaluate clinical and patient outcomes and predict what lies ahead. When a new competitor is launched RWE head-to-head comparisons can provide timely and efficient data allowing defensive measures to be taken, and to reinforce the value of the drug.

**MATURE PHASE**

The mature phase of the drug involves extending the product life cycle via adapting the product for new indications or
differentiating the product in a busy marketplace. Product lifecycle management strategies are increasingly key in the face of competition from generics. RWE data collection may be a key method of differentiating against competitors, showing added value and positive patient outcomes. Patient experience and feedback collected within RWE programmes can provide valuable insights towards directions that can extend the lifecycle of the product e.g. extended release versions, fixed-dose combinations etc.\textsuperscript{12,13}

There is a place for RWE throughout the product lifecycle and RWE should be considered as part of the marketing mix within any brand plan. To start with, RWE should be considered at an early stage to help understand and shape the value story to meet the needs of the relevant stakeholders including prescribers, payors and patient groups. Gaps in data and knowledge should be identified by evaluating the existing literature, the competitive threats and the characteristics of the product within its market. With these foundations, RWE collection and analysis can be designed based upon the pertinent questions that need answering.

A cross-functional and collaborative approach is required to realise the potential of RWE and reap its benefits. Many companies have not yet taken the steps to accommodate RWE as part of their strategic planning and should take action to maintain their competitiveness in coming years.

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