



So What Exactly is Your Real-World Data Strategy?

Rob Thwaites, MA, MCom, Vice President, Health Economics and Epidemiology

Fail to prepare... and prepare to fail. This risk hangs over drug companies without a planned approach to using real-world data to support the products they develop and attempt to commercialize. Why is such data crucial to success, and what should a company do to build a real-world data strategy?

Every new compound needs an evidence strategy, whether that is a stand-alone plan or an integral part of the overall commercial strategy for the compound. Behind the efforts to create the evidence is a need for data: synthesis of existing data; new clinical data; and new “real-world” data (RWD). New RWD is an increasingly important component of this package, particularly for filling gaps left by other sources. It is, for

example, essential not only to inform internal, company decisions, where no guidance is available either from the literature or from earlier in-house research, but also to inform external, healthcare decisions on the use of a new product in clinical practice where no insights can be gained from the clinical development program.

All this means that collecting the real-world data efficiently and effectively is critical to the success of a new product as it moves through research and development into clinical practice. Investments in RWD studies can, however, be time-consuming, costly, and subject to various uncertainties. Companies can easily find themselves falling behind unless they plan ahead for data to be available in good time for decision making.

But there is another dimension to this. Ideally planning for RWD should apply not only to a given compound, but also for needs *across* compounds and *across* development programs. With a real-world data strategy that can support one or more compounds, a company can capture savings in time and cost (e.g., in acquiring and analyzing data), and through time can build its expertise in using the data for analyses that will, in turn, be more effective in meeting decision makers’ demands for evidence.

DEVELOPING AND IMPLEMENTING A RWD STRATEGY

There are some examples of individual companies adopting approaches to RWD that support multiple products

or multiple departments, driven at least in part by the increasing demands from healthcare decision makers for evidence based on RWD. With the current excitement about “big data” and its possibilities in both healthcare and in life sciences, senior management is increasingly interested in exploring possibilities with data and in partnering with organizations that have already built RWD-related capabilities.

Over the last few years, a large biopharmaceutical company has built upon its existing in-house expertise in RWD by establishing strategic relationships with organizations with strengths in data and analytics. In 2011, the company and a health outcomes company launched a collaboration¹ to conduct real-world studies — prospective and retrospective observational studies on disease states as well as studies to compare the effectiveness of treatments — to support research for new compounds as well as for drugs already on the market. In the following year, the company went on to announce agreements with another private data provider and a public data provider in the UK (the Health and Social Care Information Centre).

The company’s strategy does not simply rely on data and expertise from these three partners, as it continues to conduct and publish studies using its own expertise and with other collaborators for specific projects. Recently, for example, the company published results from a novel piece of work to link information across several different datasets in the UK (the MINAP and GPRD registries, the HES hospital data, and the ONS mortality data).² Overall, therefore, the company’s RWD strategy supports multiple disease areas and is based on multiple collaborations.

This is only one example of a number of companies that have invested in strategic approaches to the use and development of RWD. In another large pharmaceutical company, for example,

the R&D division has developed a RWD strategy focusing on capability building. While the company does have a centralized approach to in-licensing and accessing data, it has identified a widespread lack of awareness and skills in understanding how the data can be harnessed as a limiting factor in taking advantage of RWD. Building these capabilities is a long process, but interest is spreading within the company from those groups most familiar working with observational data, including Epidemiology and Health Economics and Outcomes Research (HEOR) to additional groups, such as Safety and Regulatory where there have been increased requirements from their stakeholders. Crucially, data needs are still driven by needs of individual brand teams and so the broader RWD strategy ties back to the evidence and commercial strategies for a particular product.

Companies are also looking for opportunities to help guide earlier research activities. Another large biopharmaceutical company recently acquired a company with success in identifying genetic risk factors in a range of diseases using detailed genetic and medical information from hundreds of thousands of individuals. The company expects that this will increase its ability to identify and validate human disease targets, in turn leading to efficiencies in drug development.³

BENEFITS OF A RWD STRATEGY

A RWD strategy can open up a range of benefits to a company, with studies using RWD — supporting activities across the breadth of the product lifecycle from research through development and post-launch — more easily conducted. A few examples are listed below.

- In research, the use of genomic, proteomic and clinical data to better understand diseases, identify targets and predict the likely consequences of treatments;

- In clinical development, new applications for evaluating protocol feasibility and identifying patients promise to cut recruitment times significantly from recent experience (example of an early pilot*);
- In pharmacovigilance, new technologies are allowing signals to be identified earlier and hypotheses based on outcomes in clinical practice to be generated sooner.

An important thing to recognize here is that a company does not have to have all the skills in-house — there are organizations that focus on specific capabilities and who can provide the services at lower cost and with greater expertise than if a company built the capabilities internally.

More broadly, by thinking strategically, companies can work together to harness the power of RWD in the future. Many of the underlying capabilities needed to process and analyze RWD are still in development and several companies have made a strategic commitment to contribute to multi-company or industry-level efforts, such as the recently completed Observational Medicines Outcomes Partnership (OMOP) in the U.S. and the range of ongoing projects relying upon electronic data under the Innovative Medicines Initiative (IMI) in Europe. Companies’ investments in these activities form part of their long-term RWD strategy.

RWD STRATEGY — STILL UNCOMMON

Strategic initiatives to be more systematic and effective in the use of RWD are not new.

- Since the 1990s, payers in the U.S. have employed their internal data in retrospective research to understand, for example, patterns of utilization and associated costs for existing therapies and for modeling the impact of new therapies.
- In the early years of the last decade, a biopharmaceutical company launched its Healthcare Information

Factory,⁵ bringing together IT experience, data sources and in-house analytical capabilities.⁶ The company subsequently published many studies using the U.S. database cited, across a range of disease areas, and worked with data from a number of other countries.

Despite this, in our experience, such a strategic approach to building a company-level RWD capability is still the exception rather than the rule in industry. While there are many examples of companies successfully using RWD in projects to create evidence in support of a particular drug or device, we have come across very few documented, company-wide, RWD strategies. This is surprising, given that publicly available patient level data has been around for a couple of decades now and given the more recent excitement about “Big Data”.


RWD STRATEGY – KEY FACTORS FOR SUCCESS

From the work we have done with clients, there are many lessons that we have learned and several critical insights into the design and implementation of a RWD strategy that we have gleaned. Design is not straightforward — there is no standard blueprint to work from —

and implementation will take years rather than months. Outlined below are some of the critical factors that will lead to success.

- **Define the scope of the strategy.** Find ways to focus the strategy, limiting the area of the organization involved, or data types, or geography, to make the new approach manageable at the start.
- **Secure engagement from the top.** Ensure active and vocal senior management support for the strategy, as this will be essential for investment and for buy-in from others in the organization who will need to be involved in RWD activities.
- **Develop champions at all levels.** Work with those in the organization who understand the potential of RWD to help communicate the possible uses of RWD and overcome reluctance in project teams to consider RWD work.
- **Use while you build.** Communicate early ‘wins’ with the first data or partnerships to the company to highlight the value and win additional support.
- **Establish partnerships.** Actively seek out opportunities to work with others who have data, technology, or capabilities to take advantage of their strengths and to learn from their experiences and knowledge.

- **Build and share capabilities.** As this is a journey that will take time, foster the growth of the in-house skills and experience, and share this expertise across relevant teams within the company.

With the explosion in the availability of RWD, particularly in North America and Europe, life sciences companies are recognizing the many opportunities that these resources offer in research and development. In most cases the responses are piecemeal — the development organization commissions an epidemiology study to better understand the course of a disease and its treatment; the HEOR team commissions a chart review to understand treatment patterns and resource use to help with budget impact analyses; the commercial function commissions a database study to understand adherence patterns with a recently launched drug. Few companies have begun to consider how to engage across multiple parts of the organization or to invest in capabilities to capture the opportunities that are emerging from newer data sources. A dedicated RWD strategy can provide the framework not only for investments in the capabilities needed but also for encouraging groups across the organization to plan for greater and more effective use of RWD. 

For more information, please contact Rob.Thwaites@evidera.com.

References

- ¹ Press release. Available at: <http://www.astrazeneca.com/Partnering/latest-news/Article/2011--az-and-healthcare>. Accessed Feb. 20, 2014.
- ² Boggon R, van Staa TP, Timmis A, Hemingway H, Ray KK, Begg A, Emmas C, Fox KAA. Clopidogrel Discontinuation after Acute Coronary Syndromes: Frequency, Predictors and associations with Death and Myocardial Infarction — A Hospital Registry-Primary Care Linked Cohort (MINAP-GPRD). *Eur Heart J*. 2011 October; 32(19): 2376–2386. (*The Myocardial Ischaemia National Audit Project (MINAP) registry in the UK records data, including discharge medications, for patients with MI in all 230 acute hospital trusts in England and Wales, the General Practice Research Database (GPRD) containing anonymized primary care medical records, the Hospital Episode Statistics (HES) data, and mortality data from the Office of National Statistics.*)
- ³ Amgen 2012 Annual Report. Available at: http://www.ext.amgen.com/pdfs/investors/Investors_2012_AnnualReport.pdf. Accessed Feb. 20, 2014.
- ⁴ The UK CRC Connecting for Health Advisory Group report, The Report of the Research Simulations, May 2007. Available at: <http://www.ukcrc.org/research-infrastructure/e-health-research/rd-advisory-group/>. Accessed Jun 12, 2013.
- ⁵ PRNewswire. Global Pharmaceutical Company Licenses IHCIS Managed Care Benchmark Database. Available at: <http://www.prnewswire.com/news-releases/global-pharmaceutical-company-licenses-ihcis-managed-care-benchmark-database-73692587.html>. Accessed Feb. 20, 2014.
- ⁶ Balekdjian D, Russo M. Show Us the Value: A New Survey Reveals What MCOs and PBMs Really Want: Products with Value — and the Clinical Proof that Demonstrates Their Worth. *Pharmaceutical Executive*. Sep 2003. Available at: <http://www.pharmexec.com/pharmexec/article/articleDetail.jsp?id=68657&sk=&date=&pageID=3>. Accessed Feb. 20, 2014.