



Reader ROI

- Pharmaceutical companies usually focus on collecting, managing, and analyzing the data for a specific trial. Only rarely do companies think to analyze clinical data longitudinally across trials.
- The challenge to pharmaceutical and biotechnology organizations is to turn the submission and post-submission data into valuable information that can guide the organization's medical and business decisions.
- The key to leveraging the value of data from clinical trials is to take the first step.

Leveraging the Value of Data from Clinical Trials

Today, pharmaceutical companies engaged in clinical development usually focus on collecting data for a specific trial, analyzing data for a specific submission, and collecting post-marketing data for reporting to health authorities. Traditionally, the approach has been on a trial-by-trial basis; i.e., managing and analyzing the data from each trial as a single entity. Companies may try to use these individual trial data to view early patient demographics to verify inclusion criteria, act upon latest patient recruitment data, and optimize protocol design based on prior experience with a similar study. However, only rarely do companies think to analyze clinical data longitudinally across trials.

Pharmaceutical companies make significant investments—money, time, and people—in clinical trials. Yet, once the submission is completed, most companies simply archive the data and toss the ball over to medical affairs. Little, if any, effort is made to add value to these data by augmenting them with data from phase IIIb and post-marketing trials. There are significant benefits to be realized if this action is taken. The adage that “the whole is greater than the sum of its parts” applies. The challenge to pharmaceutical and biotechnology organizations is to turn the submission and post-submission data into valuable information that can guide the organization's medical and business decisions.

Some in the industry are beginning to understand how the value of clinical patient data can be enhanced when it is integrated with information from other related sources. Some companies have shown early interest in developing clinical data warehouses (CDW) or products that support a clinical data repository (CDR). Either can help to optimize clinical development and promote mining of clinical data for new insights. Benefits can come from viewing all data to identify trends and improve future trials, to identify outcome, and to identify potential safety implications. However, much more can be done in this area.

The pharmaceutical industry must find ways to leverage its core strengths to:

- Protect its existing products' market share
- Create the most effective environment for new product introductions
- Respond more quickly to competitive threats
- Provide feedback to discovery and development

One of the core strengths of pharmaceutical companies is the fact that they possess a wealth of clinical data just waiting to be leveraged. This data can be analyzed across trials to develop insights that sales and marketing can use, or that can influence new research initiatives.

Imagine a sponsor being able to really exploit the value of these data. A pharmaceutical company's ability to quickly and effectively answer post-submission, post-approval health authority questions may mean the difference between market success and failure. New end points might be identified that will have a positive impact on the product label, possibly improving product positioning. New insights into efficacy might be identified when data from trials of more defined patient populations are augmented with patient data from large phase IV trials, where patients more closely reflect the “general population.”

A sponsor could answer product questions that otherwise may have required an additional clinical trial. Insights gleaned from the aggregated data could provide information that can be used to ward off competitive threats. Mining the aggregated data could result in the identification of a promising new indication, thus increasing the product's value.

An article¹ describing the sumatriptan/naratriptan aggregated patient (SNAP) database states that, “Pooled data from multiple clinical trials can provide information for medical decision-making that typically cannot be derived from a single clinical trial.” The article goes on to say that, “By increasing the sample size beyond that achievable in a single clinical trial, pooling individual-patient data from multiple trials provides additional statistical power to detect possible effects of study medication, confers the ability to detect rare outcomes, and facilitates evaluation of effects among subsets of patients.” The discipline and rigor of pharmaceutical sponsored trials should encourage meta analysis and data mining.

The aggregation of pre- and post- submission clinical data represents opportunities for success that literally span the entire product life cycle. The key to leveraging the value of data from clinical trials is to take the first step and be willing to critically examine the way things are being done now. If this step is taken, one can begin to reap the benefits and rewards of aggregated clinical trial data.

¹Source: Barrows, C, Saunders, W, Austin, R, Putnam, G & Mansbach, H (2004) The sumatriptan/naratriptan aggregated patient (SNAP) database: aggregation, validation and application. *Cephalalgia* **24** (7), 586–595.



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