



Medical Safety Data Assessment and Reporting in the Pharmaceutical and Biotechnology Industries - High Risk, Labor Intensive Work: When is Outsourcing a Viable Solution?

Zel Dolinsky, Ph.D.

Individuals tasked with evaluating and reporting safety data (i.e., adverse drug event or ADE) in the Pharmaceutical and Biotechnology (Pharma and Biotech) industries have an extremely difficult task with high-risk implications. They are charged with: **Accessing/Collecting** subjects' ADE data; **Assigning** these data to body system; **Determining** seriousness, attribution, and "expectedness"; **Interpreting** the clinical relevance of the data vis-à-vis the drug's mechanism of action, effects of concomitant medications &/or disease state and epidemiological context; **Recording, Tracking** and Trending data; **Reporting Results** to regulatory authorities within specified timelines; and ultimately, playing a key role in determining the **Risk versus Benefit** of the drug's development and continued marketing. Individuals carrying out these functions need to have extensive clinical training, meticulous attention to detail, and the ability to evaluate, prioritize and trend safety concerns within large amounts of data.

Safety responsibilities need to be performed in a coordinated fashion, matching resources to timelines for multiple developmental and marketed products. Quality must be maintained while also adhering to complex regulatory requirements. This requires the ability to predict need, project adequate and flexible resources and costs accurately, and the capacity to build infrastructure responsive to constantly changing workloads and regulatory requirements.

The complexity and workload associated with ADE assessment and reporting will be complicated by the FDA's "TOME" (Federal Register - vol. 68, #50, 3/14/03: Pgs. 12406-12497). This 91-page guidance imposes the attribution of presumed causality for many more adverse events. In addition, the guidance requires increased documentation and subsequent contacts and follow-ups by medical professionals. The resulting increase in the number of expedited clinical trial ADEs to be reported, combined with the customization and changes to the periodicity of the Periodic Safety Update Reports (PSUR's) recommended by the

TOME, would dramatically increase the burden on companies to comply with this guidance.

The potentially increased and rapidly changing demand for resources and the sheer volume of data inherent in safety monitoring makes this task, at this time, a prime candidate for outsourcing. Each can be a substantive factor in altering the conduct of on-going clinical trials and/or addressing issues associated with post marketing surveillance (PMS) and have major safety and financial ramifications. However, the Pharma and Biotech industries have been reluctant to outsource safety work for the following reasons:

1. Professional personnel committed to strict attention to detail are needed to process safety data;
2. The complexity of safety data collection, evaluation, recording, tracking, interpretation and reporting requires extensive experience;
3. Staying informed of and adhering to changing regulations is essential;
4. Advanced technology for recording, tracking, and auditing procedures must be utilized;
5. A highly secure and quality driven infrastructure to oversee the safety process is required;
6. There is potentially a high risk of litigation or regulatory consequences associated with incorrect collection, interpretation, recording, tracking and reporting of safety data.

When in-house resources are taxed, and traditional vendors are unavailable, it becomes imperative to explore other possibilities. There are other industries embracing similar quality standards and utilizing parallel processes but with whom a connection has not yet been made with Pharma and Biotech industries. One example is Medical Research Consultants (MRC), a previously untapped source of skills, resources and infrastructure- MRC processes vast amounts of clinical data to precise client specification for medical litigation support. They engage medical professionals to process highly complex data, capitalizing on cutting edge technology in a highly secured environment. MRC therefore would be an ideal candidate for Pharma and Biotech safety data outsourcing.

Although MRC is not a Pharma or Biotech development company it is run and staffed by health care professionals. Because of its 21-year tradition of providing medical litigation support MRC is extremely experienced in the collection, recording, tracking, interpretation, trending and reporting of clinical data. In fact it was the company that processed the extensive amount of PMS data for the fen-phen litigation.

MRCs clinical workforce is composed of nurses with an average 10+ years of clinical experience and extensive skill determining relevant clinical trends in medical data. Their work is always conducted within a paperless environment ensuring confidentiality and security. In addition, MRC has the capacity, flexibility and infrastructure to scale up and meet the demands of increasing workloads, will provide a dedicated process team and become an extension of their client's operation.

State-of-the-art technology plays a key role in efficient and error free operations; data are translated to images and processes are in place to store and manage cases confidentially, safely and securely. Records are accessible 24/7 via a secured web browser to clients who have been approved and assigned access rights to their records. In addition, MRC has the capability of entering data directly into clients' safety databases using secure technology.

To specifically address PMS, MRC can use its call center facilities with an active query process to collect, verify, monitor and triage ADE / safety issues reported from multiple sources (i.e., patients, physicians, etc.). Nurses trained in regulated and comprehensive legal reporting techniques staff the MRC call center. With a call center in place MRC has the ability to identify safety concerns in PMS information rapidly so that appropriate responses can be taken to address these concerns and minimize potential for litigation and/or lost revenue. MRC has the ability to respond to changes in safety regulations (e.g., TOME) by increasing the number of appropriately trained staff and has mechanisms in place (e.g., call center) to address requirements of this guidance.

In summary, the Pharma and Biotech industries have a number of issues that make them reluctant to outsource safety data. However, they should be aware that other organizations exist that address their specific concerns. Third party organizations that meet stringent criteria are excellent candidates to assist the Pharma and Biotech industry in the difficult and high-risk tasks associated with safety data processing.

MRC was founded in 1983 by Doreen Wise, R.N., Ed.D. Based in Houston, Texas, MRC is the largest nurse-owned and operated medical/legal consulting firm in the United States. For additional information about MRC, contact Doreen Wise at 713-528-6326 or The Avoca Group at 609-252-9020. (www.mrchouston.com; www.theavocagroup.com)