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## SAS Takes Lifecycle View of Patient Safety Data

BY ANN NEUER

The pharmaceutical industry and regulatory agencies are sharpening their focus on patient safety through intense efforts to improve the way safety data are collected, analyzed and interpreted. And there is a long way to go, says **Jason Burke**, global director of the health and life sciences market segments at SAS. "Today, most organizations do separate analyses for drugs before and after approval. This is a challenge because it may not be obvious how the lifecycle of a drug looks when safety analyses are conducted using separate pre- and post-approval processes and systems," Burke explains.

A comprehensive lifecycle view of the safety performance of a drug is what is needed to provide a more repeatable, standardized, and auditable approach for exploring safety signals. The FDA is steering the market in this direction with the release of various guidances intended to improve how the agency disseminates safety information, how adverse events are to be reported, and how reviewers are to conduct the clinical safety reviews for the new drug application (NDA) and biologics license application (BLA) review processes. There is also the Sentinel Initiative, launched by the FDA in May to develop a national strategy for monitor-

ing medical product safety, a nod to the emerging science of safety.

"The agency is driving toward getting a better understanding of the comprehensive view of what safety looks like over the entire history of the drug," Burke says.

With all this headwind, SAS is on board with its just-released SAS for Patient Safety, a comprehensive solution designed to help users comply with recent FDA guidances by offering advanced analytics for signal detection and pharmacovigilance. The solution consists of a collection of SAS software that is implemented in conjunction with consulting services. It offers capabilities such as standardized safety reporting that leverages standards from the Clinical Data Interchange Standards Consortium (CDISC) and FDA guidances, visualization capabilities that enable researchers to understand patient safety data, and automated signal detection of published as well as SAS-developed signal detection algorithms. "The intent is to remove the need to manually imple-



ment commonly used safety algorithms by rolling them into the solution," Burke comments.

An important feature of SAS for Patient Safety is that it allows for data aggregation and data integration, to enable standardization and to bring together information from disparate sources into a consistent repository. According to Burke, pharmaceutical companies typically rely on transactional safety systems within silos to produce periodic reports. "This siloed approach creates challenges for companies in terms of aggregating information from many sources, cleaning the data, and using standardized structures to report them," he says.

The technology behind the integration capability is the newly launched SAS Clinical Data Integration server, a platform that defines and automates processes for aggregating clinical data through the use of standards such as those of CDISC. "With this platform, SAS can provide a bridge across whatever sources of safety information a pharmaceutical company might be using to create a 360-degree view of the profile of the drug. We created SAS for Patient Safety in response to what we have seen as a sea change in the industry focusing on safety," Burke says.