



## Business Impact

“Consumer and regulatory pressure to improve the safety of marketed therapies are driving companies to adopt a more comprehensive, analytically driven view of a therapy’s complete lifecycle safety profile.”

Alan Louie, PhD  
Research Director  
IDC Health Insights

## Challenges

- **Divergent systems and data.** Silos of information dispersed across multiple systems and nonstandard data limit the ability to derive scientific insights.
- **Lack of predictability.** Life sciences companies sometimes struggle to detect, predict and medically evaluate potential safety signals.
- **Incomplete or unstructured data.** Because much of the available data is incomplete (i.e., missing or inconsistent values) or comes in the form of unstructured text, life sciences companies are unable to quickly derive safety insight from it.

## How can we comprehensively monitor the safety profile of our medications?

### YOUR GOAL: Improve patient safety and health outcomes

Regulatory authorities, patients, health care professionals, government officials and the media are increasing their scrutiny of life sciences companies based on continuing, high-profile drug safety issues. Highly publicized safety concerns and market withdrawals of commonly prescribed medications have focused increased attention on the issue of drug safety. In the US, the FDA has the authority to require a Risk Evaluation and Mitigation Strategy (REMS) to ensure that the benefits of a medication outweigh its risks. Life sciences companies are being challenged to actively address the safety of their therapies to maintain their solid reputations, scientific integrity, shareholder confidence and public trust.

Now more than ever, health care professionals and patients must continuously evaluate risks against benefits when making decisions about the right treatments. Early detection and evaluation of safety concerns reduce the potential impact of a major public relations and liability issue for the company and industry. All therapies carry some risks, but by identifying those risks as early as possible, life sciences companies have the best opportunity to develop and implement an appropriate course of action.

### OUR APPROACH

Companies are under increasing pressure to identify potential safety problems before they become a threat to public health and apparent to clinicians, patients and regulatory authorities. We approach the problem by providing analytics software and services to help you:

- **Aggregate and integrate drug safety data from virtually any source** and then transform, cleanse and standardize the data so it is ready for further safety analysis and signal detection.
- **Drive better drug development decisions and mitigate potential post-marketing risks** by applying advanced analytical methods and algorithms throughout a drug’s life cycle to proactively spot pre-approval safety signals and emerging post-market safety concerns.
- **Uncover hidden insights in unstructured sources, such as call center notes,** by using text mining capabilities to proactively scan unstructured text for insights on safety signals, customer concerns and service or product needs.
- **Tap into the true early-warning system that social media channels may provide** by applying text mining and analytics to real-time social media data about your medications.

The ability to analyze risk vs. benefit for medical therapies is at a crossroads that demands innovation. SAS® provides the data management and advanced analytics to drive that drug safety innovation by transforming diverse data sources for analysis so you can accurately predict and then medically investigate drug safety signals.



## THE SAS® DIFFERENCE: Accurate, consistent and reliable analysis

SAS assures accurate, consistent and reliable analysis of biopharmaceutical safety data and information. Only SAS provides:

- **Comprehensive data management.** SAS eases access to standard, trusted safety data regardless of format, computing platform or location.
- **World-class analytics.** While less rigorous analytics work for certain applications, the critical nature of drug safety demands the best analytics available. SAS provides the best analytic and reporting technologies for drug safety evaluation.
- **Domain expertise.** SAS has invested heavily in domain experts who understand the critical nature of drug safety.

SAS is globally recognized as the industry leader in business analytics and the de facto standard for clinical data analysis and reporting in life sciences. For more than 34 years, life sciences companies have used SAS to derive greater insight from information. By providing a way to access, transform, manage and analyze your data more efficiently and effectively, SAS enables you to transform biomedical data into clinical insights quickly.

### CASE STUDY: A major life sciences company

#### Situation

A major life sciences company wanted to improve its post-marketing safety surveillance process.

#### Solution

SAS provided the company with an analytics solution that included:

- Integration of all safety data for analysis.
- Improved identification and prediction of safety signals.
- Signal detection algorithms that provide unique capabilities to understand the safety profiles of the company's therapies.

#### Results

The company now has a more effective and proactive post-marketing safety surveillance program using advanced signal detection algorithms that provide unparalleled analytics to address pharmacovigilance.

#### What if you could ...

##### Aggregate and integrate drug safety data from any source

What if your organization could integrate and cleanse disparate drug safety data from virtually any source?

##### Proactively detect safety signals

What if you could apply world-class analytic capabilities to provide proactive safety surveillance for your products?

##### Scan unstructured text for safety signals

What if you could mine and analyze the real-time safety data available through your customer contact center or social media?

#### You can. SAS gives you THE POWER TO KNOW®.

### SAS FACTS

- SAS is the de facto industry standard for clinical data analysis and reporting in the life sciences industry.
- For more than 34 years, life sciences companies have used SAS to derive greater insight from information.
- SAS has been a leader in the definition and implementation of industry standards since 2000.

Learn more about SAS software and services for life sciences at: [www.sas.com/industry/pharma/](http://www.sas.com/industry/pharma/)



SAS Institute Inc. World Headquarters +1 919 677 8000

To contact your local SAS office, please visit: [www.sas.com/offices](http://www.sas.com/offices)

SAS and all other SAS Institute Inc. product or service names are registered trademarks or trademarks of SAS Institute Inc. in the USA and other countries. © indicates USA registration. Other brand and product names are trademarks of their respective companies. Copyright © 2010, SAS Institute Inc. All rights reserved. 104650\_S56427.0810