Rapid Response To Adverse Event Reports With Cloud Technology
Biopharma companies need to monitor for adverse events to ensure patient safety and to remain in compliance with regulatory requirements, both in clinical trials and after a drug goes on the market. Serious adverse events must be reported to the FDA within 24 hours. But today, a lack of coordination across adverse event data sources creates challenges for manual, human-centered systems to track and report events with the speed and accuracy needed in a fast-moving environment. Recognizing that, companies are leveraging cloud technologies to help streamline and automate their processes.

The shortcomings of manual, human-centered systems have been exposed by the rapid increase in adverse event report volume in recent years. Users submitted 2.2 million reports to the FDA Adverse Event Reporting System in 2019, up from less than 500,000 reports in 2009.¹

Adverse event reports come from multiple sources. Healthcare providers submit reports when they see adverse events in clinical trials and routine care. Patients call 1-800 numbers to report their symptoms for adverse events related to drugs on the market. Then, the representative triages these calls to log them as mild events or escalate them when severe.

Part of the growth in reporting volumes can also be attributed to new data streams. Social media, telemedicine visits, and medical chatbots are emerging sources of adverse event data that compound traditional reporting channels.

Companies have tried to handle the growing volumes of adverse event reports using their existing manual processes but have found this approach difficult to sustain. Manual aggregation and interpretation of adverse event data, which comes to biopharma companies
in many formats and languages, entails many time-consuming steps. Delays and errors can happen at each step, challenging biopharma and medical device companies’ ability to keep patients safe through the rapid identification of emerging issues.

Coping with surging volumes

In 2020, as COVID-19 spread, many sponsors paused clinical trials, in part to protect participants and enable healthcare providers to focus on the pandemic. The resumption of those studies, coupled with the initiation of new trials delayed by COVID-19, caused a sudden influx of adverse event data.

This influx is expected to grow even larger as COVID-19 vaccines are rolled out to billions of people, as vaccines typically result in a larger volume of reported adverse events. One expert warned a “tidal wave” of adverse event reports would hit the “already strained system” as COVID-19 vaccines are rolled out. Manual systems lack the scalability needed to cope with such surges in volumes.

Recognizing that, forward-thinking companies are leveraging AWS cloud-based artificial intelligence (AI) and machine learning (ML) technologies to better handle the growing workload. Technology advancements complement human workers by automating and adding intelligence to required tasks. As an example, natural language processing (NLP) can be applied to assess reports across multiple languages in order to extract those that need further review.

Rising volumes are driving more companies to leverage such technology, enabling them to automate call centers, error-proof workflows, and otherwise adapt to a data-rich world using validated cloud solutions.

Cloud-based solutions for adverse event reports

Automating call centers

There remains a need for systems and processes capable of handling the traditional adverse event reporting that happens via patients or healthcare providers calling contact centers. Biopharma companies are used to working with such data, but there remain significant opportunities for improvement. AWS
addresses those opportunities with AI services that automate information capture, provide quick analysis, and limit errors to help agents triage calls and escalate quickly when necessary.

Call centers can be set up with Amazon Connect, an omnichannel cloud contact center that provides a seamless experience across voice and chat for customers and agents. Because Amazon Connect is AI-enabled by default, agents can immediately use AWS AI services to automate interactions and improve customer service. For example, calls can be intelligently routed to the best agent using Amazon Lex. This service builds conversational interfaces into any application with speech-to-text and natural language understanding (NLU).

Call centers can also transcribe calls quickly and accurately with Amazon Transcribe Medical, a HIPAA-eligible speech-to-text service for the medical industry. The HIPAA-eligible natural language processing (NLP) service, Amazon Comprehend Medical, uses ML to extract relevant medical information from the unstructured call center text, accelerating the identification and tagging of events. Finally, Amazon SageMaker, a ML service used to build, train, and deploy ML models, can quickly and accurately flag adverse events for human experts’ follow-up.

Amgen is among the companies currently deploying this technology. Working with AWS, Amgen used Amazon SageMaker to develop ML models to do full ML-based auditing of incoming potential adverse events from call-center records and showed top-performing models achieved 98% accuracy.

Amgen is also exploring extracting safety events from call center recordings. “Amazon Transcribe Medical produces text transcripts from recorded calls that will allow us to extract meaningful insights about medicines and any reported side effects. In this way, we will be able to quickly detect, collect, assess, report, and monitor adverse effects to the benefit of patients globally,” George Seegan, Senior Data Scientist at Amgen, said.³

“Many of the safety events we are looking for are rare, and we look for them in places like medical and scientific literature, whose volume is increasing tremendously. Some of these automated tools will help us find those needles in those haystacks,” Seegan said.

Processing written clinical records
Call centers are just one of the adverse event data streams biopharma companies need to master. Healthcare provider notes,
shared via clinical trial documents and electronic medical records, are another source of reports that threaten to overstretch manual systems’ capabilities. To mitigate that threat, biopharma companies use the speed, scalability, and security of cloud technology to improve their processes.

Eli Lilly identified the need to rethink its approach to handling written sources of adverse event reports in 2016. Adverse event information was entering Lilly from a range of sources, including medical records and handwritten physician notes. It fell to the healthcare professionals on Lilly’s pharmacovigilance team to manually sort through the incoming information to determine the seriousness of a case. That labor-intensive process needed to happen before Lilly could even begin to consider what actions it should take in response to a report.

Working with PwC, an AWS Partner, Lilly leveraged cloud-based technologies to automate and improve the efficiency of historically manual processes. The new Lilly workflow uses Amazon Comprehend Medical to read and recognize key information in a data lake populated by the various sources of adverse event reports that flow into the company. In doing so, the NLP models surface data and analysis for review by humans and interpret information using machine learning and rules-based models. The next steps are determined by the risk and completeness of a report, as interpreted by the model and verified by the user.

Lilly has realized multiple benefits from the system. It now takes seconds to process a case, down from up to two hours using the old manual system. The time-saving means the system has delivered on Lilly’s hopes that it would gain an “improved ability to manage future demand surges,” such as biopharma companies face due to COVID-19, and freed up trained medical professionals to perform more fulfilling, higher-value work.

“We’re saving time and we’re saving money, but we’re also giving people much better jobs. They’re focusing on things that are important to them,” JR Burch, Manager of Information and Digital Solutions at Lilly, said.

Lilly’s experience illustrates the value of cloud technologies to the processing of written records. Biopharma companies can quickly and accurately extract data from images and documents without any manual effort and create models that enable the efficient processing of adverse event reports by using fully-managed services such as Amazon Comprehend Medical, Amazon SageMaker, and Amazon Textract.
Mastering emerging data streams

In the past, call centers and provider notes were the primary sources of adverse event reports. That is no longer true. Today, biopharma companies need to monitor a growing number of other sources, including social media. The data volumes carried by those streams are larger still, making systems capable of working quickly and accurately at scale even more critical for success.

“Social media as a source is very challenging and actually costly to monitor because of the very high volume of data, because of complex and improper language use, and in general just human creativity online,” Damir Bucar, Product Engineer at Novartis, said.6

The volume of posts makes social media the ultimate needle-in-a-haystack problem for biopharma pharmacovigilance teams. An analysis of almost 1 million Facebook and Twitter posts found one adverse event discussed on social media before being reported to the FDA Adverse Event Reporting System, showing both the value of the data source and the challenge of extracting timely insights from it.7

Volume is only one of the challenges posed by social media. In social media posts, people construct sentences using different words, spelling and grammar than are typically found in traditional written communications. Slang, acronyms, and hashtags are commonplace, as is non-written communication such as emojis and images.

Novartis responded to those challenges by creating NLP models to detect potential adverse events in social media posts. Using Amazon SageMaker, Novartis created a GxP-compliant system for automatically analyzing social media posts and, based on the content and context, predicting whether they contain reports of adverse events.

The platform, AE Brain, provides real-time monitoring of Twitter, Facebook, YouTube, and other social channels. Novartis previously tasked a team of more than 120 people with manually monitoring and reporting social media posts. Automating the system improved quality and reduced the burden of repetitive manual work. Sixty percent of adverse events are processed by the AI directly as a triage mechanism, enabling people to focus on a smaller number of key events of interest. Currently, AE Brain processes around 15,000 messages per week, capturing far more data than a human team could review and increasing the quality of Novartis’ drug monitoring overall.8
Social media is part of a larger group of emerging communication forums that can contain data on adverse events, such as telemedicine visits and medical chatbots. Biopharma companies are alert to the opportunities and challenges posed by the new media.

**Conclusion**

In a fast-changing world, the agility of cloud technology is critical. Biopharma companies cannot predict, let alone control, where people will talk about their products. Still, they can set up systems that enable them to respond to new forms of communication quickly. And if billions of COVID-19 vaccine doses are administered in the upcoming years, the number of adverse event reports coming in could potentially overrun outdated systems.

Companies that follow the examples of Amgen, Lilly, and Novartis by moving to the cloud will position themselves at the forefront of efforts to improve pharmacovigilance. Partnering with mature companies that are continually building industry-specific solutions and services such as AWS will ensure they have systems with the security, scalability and global reach to efficiently handle ever-growing volumes of adverse event reports.

**References**


5. Lilly’s Journey to Touchless PV Case Management: An AI Implementation Story.


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