



FEATURE

## Your Data & You: Who Works for Whom? *The Burning Platform for Compliance Data Analytics*

By Amy Pawloski, Gillian Sutherland, and Benjamin J. Schein<sup>1</sup>

**Summary:** Almost every life science company today could likely “check the box” when it comes to having some sort of data analytics aspect of their compliance monitoring program. The question regulators will start asking companies, however, is no longer “if” a company has adopted data analyses in support of their programs, but rather, “how and to what extent?” To best safeguard the interests of their organizations, Compliance leaders should be prepared to demonstrate the ways in which their organizations are maximizing the utility of their various data sources to better prevent and deter inappropriate conduct.

Imagine that you were at a compliance conference, albeit a virtual one at the start of the pandemic, and you listened to yet another presentation about data analytics. It may be a different year, a different presenter, but the story sounded the same. Moderators and panelists were telling audience members that they should be thinking about implementing data analytics to support the compliance program. But after the conference ended, implementing a data analytics solution sounded complex, and since none of the presenters cited a “burning platform” requiring immediate action, data analytics went on the “back burner” for yet another year.

That no longer is the case and compliance data analytics now has its “burning platform.” Three main factors are responsible for this change:

1. Less than a year ago, the U.S. Department of Justice (“DOJ”) published a revised version of its guidelines

for evaluating the effectiveness of compliance programs.<sup>2</sup> The guidelines reflected a significant shift in the regulators’ expectations for companies’ use of their own data in ongoing monitoring and analyses.<sup>3</sup> With the DOJ enforcement lens shifting to a more data-driven approach when it comes to investigations, companies now are expected to know how to take advantage of their own data assets to improve their compliance programs.

2. COVID-19 changed how life sciences companies conduct promotional and non-promotional activities. Therefore, the digitalization of many company representative-related HCP interactions has impacted the variety and the complexity of data being generated and stored by company systems.
3. Technologies are becoming more powerful. The costs of processing and tools are decreasing. Simultaneously, data captured by life sciences companies is increasing in volume and variety. This all adds to the value proposition of instituting automated monitoring and data analytics solutions to support compliance efforts.

## Automated Compliance Monitoring and Data Analytics

### Key Topics Discussed at Recent Compliance Congresses

Amongst the wide range of applications for data analytics, the past year’s shifts in the business landscape have caused few areas beyond data analytics to stand out as focal points for 2021. During InformaConnect’s March 2021 Compliance Monitoring & Auditing Digital Week, more than 70% of the sessions focused exclusively or in part on automated compliance monitoring and data analytics.<sup>4</sup>

**FIGURE 1:** Summary of Key Focus Areas for Compliance Monitoring & Data Analytics

| Area                                       | Key Points  |
|--|---|
| <p><b>T&amp;E HCP Meals</b></p>            | <ul style="list-style-type: none"> <li>• This is a tried-and-true area for automated monitoring. Any company that claims to be doing data analytics has certainly implemented automated monitoring in the T&amp;E space.</li> <li>• The data is relatively consistent, easy to understand, and the rules are often binary.</li> </ul>   |
| <p><b>Speaker Programs</b></p>             | <ul style="list-style-type: none"> <li>• According to the recent HHS OIG Fraud Alert<sup>6</sup> as well as the 2020 Novartis Pharmaceuticals Corporation settlement,<sup>7</sup> companies should consider risks associated with speaker programs such as payments to external speakers, the venues, and the appropriateness of attendees.</li> <li>• As a result of the COVID-19 pandemic, the number of virtual programs conducted has markedly increased. It is anticipated that future speaker program mix will include a high percentage of virtual and hybrid programs.</li> <li>• Companies should incorporate various sources of data into their analyses to provide insights and develop Key Compliance Indicators (“KCI’s”). Joining multiple data sets is essential to uncovering insights even if only one activity is being reviewed. For example, Speaker Program automated monitoring should be pulling data not only from the Speaker Program transaction system but also incorporating data from a client’s Customer Master List, the HR system, Zip to Territory Alignments, etc.</li> </ul> |
| <p><b>Email Monitoring</b></p>             | <ul style="list-style-type: none"> <li>• The pandemic saw a 500% increase in rep-sent emails since January 2020.<sup>8</sup></li> <li>• “Email will become the connective tissue between in-person interactions and new digital engagement methods.”<sup>9</sup></li> <li>• Many companies are conducting email reviews as part of ongoing monitoring. This includes companies operating under a Corporate Integrity Agreement (“CIA”) and those that are not.</li> <li>• Some companies are doing manual email reviews based on a sample selection of messages or leveraging native Microsoft Outlook “find and search” functionality.</li> <li>• Other life science companies are leveraging third party automated tools to minimize errors and time associated with manual reviews.</li> <li>• Several companies are on the forefront of taking advantage of newer artificial intelligence (“AI”) technologies to gain deeper insights and bring further efficiencies to their email reviews.</li> </ul>   |
| <p><b>Medical Information Requests</b></p> | <ul style="list-style-type: none"> <li>• Due to COVID-19 and the implications the lockdown had on MSL-related activities, there has been a dramatic increase in medical inquiries coming from HCPs to sales representatives via virtual calls.</li> <li>• Companies are leveraging automated tools to identify potential concentrations of interest (i.e., identify potential off-label promotion or understand specific data trends).</li> </ul>   |
| <p><b>Patient Support</b></p>              | <ul style="list-style-type: none"> <li>• Patient Support maintains its spot as another top risk area. “We continue to focus on ...kickbacks to patients...and paying patient advocates to become part of the process” said Gregg Shapiro, U.S. Attorney for the District of Massachusetts.</li> <li>• There have been several settlements in the patient support space specifically around Independent Charity Patient Assistance Programs (“ICPAPs”) and Clinical Educators. Enforcement agencies stated there is significant scrutiny starting to be placed on other patient support activities (e.g., Co-Pay Programs, Travel Assistance, Patient Advocacy interactions).</li> <li>• Some companies are proactively engaging third parties to perform assessments of their patient support programs and then implementing automated monitoring and data analytics tools to aid in continually assessing compliance.</li> </ul>   |

Similarly, numerous sessions centered on this topic at last Fall’s Annual Pharmaceutical and Medical Device Ethics and Compliance Congress as well as InformaConnect’s Compliance Congress for Specialty Products. Five of the central areas that were discussed throughout the forums when it came to data analytics are displayed in Figure 1.

While these five areas may merit special attention given their inherent risks as well as operational changes in the

pandemic era, it is just as important for companies to leverage their own risk assessments to determine which other areas make the most sense to monitor. Although the previous examples highlight single stream analytics (i.e., analyze one set of data), the goal of any data-driven monitoring program is to continue to expand. This expansion enables the company to effectively triangulate multiple data sets across activities and uncover potential compliance concerns before they become significant issues.

## Staying Up to Date

### The Importance of Emerging Technologies

The push from the DOJ incentivizes compliance officers to find ways to access financial and operational data and adopt technology to better screen for risks such as Anti-Kickback Statute (“AKS”) violations which can lead to significant fines if undetected.<sup>10</sup> Technology advancements and solutions in the risk management space have exploded in recent months. Today’s automated tools utilize Artificial Intelligence (“AI”) including Machine Learning (“ML”) and Natural Language Processing (“NLP”) to enhance organizations’ capabilities as they relate to preventing and detecting potential risks (Figure 2). With the rapid pace of enhancements and capabilities, it is imperative for compliance officers to understand the capabilities as they plan the future of their compliance programs.

“When it comes to Machine Learning, think of monitoring on-line comments the way that social media sites such as Twitter or Facebook do. Unsupervised Machine Learning is employed here due to its effectiveness in dealing with adversarial adaptation (adversaries changing their behavior based on what’s flagged as non-compliant). We use the same approach in life sciences with automated compliance solutions – the system recognizes anomalies without re-training and reacts accordingly as more data continues to be fed into the tool,” said John Poulin, Chief Technology Officer at Helio Health Group.<sup>11</sup>

Life sciences compliance monitoring can apply NLP to support a wide range of targeted reviews for high volumes of abstract or complex data inputs. These inputs can include emails, call notes from field interactions, field coaching reports, verbatims,

phone calls, and other free text or unstructured data tracked across systems.

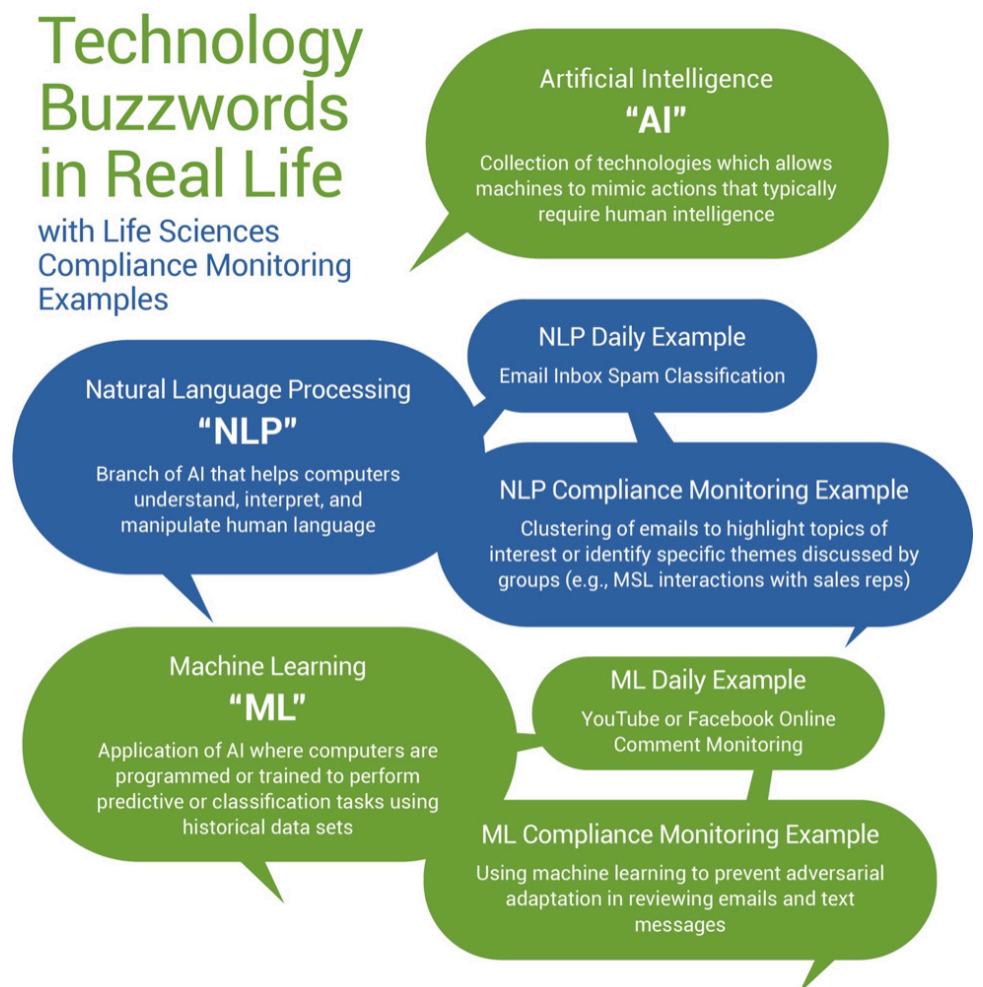
When companies decide to make an investment in a data analytics technology leveraging AI, they, in turn, are enabling their Compliance and Internal Audit teams to enhance the quality and efficiency of their compliance reviews, regardless of the review type.

## How Does Your Company Stack Up?

### Determining the Appropriate Data Analytics Program

The expectations for companies’ use of data analytics go far beyond taking one source of data to create visualizations for a Compliance Committee or Board of Directors. The focus has shifted to understanding the analytics behind it. Joining multiple disparate sets of data to create insights, highlight outliers, track KCIs, and

FIGURE 2: Data Analytics Technologies Driving Next-Generation Compliance Monitoring



**FIGURE 3:** How Does Your Compliance Data Analytics Program Stack Up?

| Starting Off  | Advanced  |
|---|---|
| Single stream data review; static charts                          | Triangulate data from multiple sources to create interactive visualizations                         |
| Violations, follow ups, and corrective actions in multiple places | A single repository for issues and resolutions with automated workflows                             |
| Internal data sets only   | Systematic leveraging of outside data sets and industry benchmarks                                  |
| All activities treated equally                                    | Perform risk-scoring of activities, transactions, HCPs, sales reps                                  |
| Repetitive monitoring of same low-risk activity                   | Analytics support evolving risk areas such as Patient Support, Medical, and Virtual HCP Engagements |
| Email monitoring done via keyword searches                        | Performing broad data reviews by leveraging ML and NLP  |
| Bolt-on compliance data analytics apart from business             | Have built-in compliance data analytics incorporated into business                                  |

identify relationship, and trends are crucial capabilities of the modern data analytics program.

Unfortunately, many companies find themselves in the difficult position of instituting a data analytics-driven compliance program without fully considering the requisite time, resources, or system updates necessary to facilitate those analytics. Compliance leaders should ask themselves if their company is utilizing data analytics to simply enhance standard reporting or is there a truly robust data analytics program in place to gather the right data to assess and identify compliance risks (Figure 3). Now more than ever, companies need to ensure that adequate consideration is given to building the functionality of their available data assets into the design of their compliance programs to stay on par with the expectations of the DOJ and OIG.

## Conclusion

In 2016, the *Policy & Medicine Compliance Update* published an article entitled, “Meet R.I.S.K.: Why Your Next Compliance Officer in Big Pharma will be a Robot!”<sup>12</sup> While no companies have hired a robot to replace their Compliance Officer to date (that we know of!), many CCOs are relying more and more on robot-like technologies (including Artificial Intelligence) to provide crucial insights in support of their Compliance programs. The 2016 article noted “[r]isk professionals spend 80% or more of their time focused on high frequency, low impact risks because it is easy to capture yet only creates a false sense of security.”<sup>13</sup>

Since that time, and with the further encouragement of the recent DOJ guidance, compliance program leaders are starting to shift from operationalizing easily available data sets to monitor lower risk activities to truly analyzing the full scope of insights available from all their available data. In a sense, they are starting to let the data work for them, rather than spending all their time working on the data to enable monitoring activities. While technology and data analytics will never fully replace Compliance Officers, supporting these individuals and their teams with the available advancements in data analytics technology is the best way for a company to cost-effectively mitigate organizational risks on a continuous basis.

## References

- 1 Ms. Pawloski is Vice President & General Manager, HelioPDR for Helio Argos. Helio Argos is the developer of HelioPDR, a proprietary automated compliance data analytics tool which leverages integrated data to identify and address compliance risk through Plan, Detect, and Respond. Helio Argos is a subsidiary of Helio Health Group. Ms. Pawloski is also President, Strategic Versatility, an independent life sciences consulting practice focused on advising clients on healthcare compliance topics. Ms. Sutherland and Mr. Schein are Associates at Helio Health Group which is a management consulting and small data engineering - centric firm that utilizes its broad portfolio of industry experience to provide strategic and operational compliance insights to stakeholders across the Commercial, Medical, and Patient Services areas of Life Sciences organizations.
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- 11 Mr. Poulin is Chief Technology Officer at Helio Health Group. For a description of Helio Health Group see *Id* at 1.
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