



## Are Life Science Companies Truly Managing Compliance Risks?

### *Becoming Data Ready*

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**Summary:** Risk management has been applied in many areas of life sciences, successfully mitigating and managing risks ranging from strategies to manufacturing. However, more can be done for life science compliance to further adopt the Risk Assessment & Management Plan (“RAMP”) process. We will explore the value of performing data analytics and how life science companies implement analytics at each step of the RAMP lifecycle for an effective compliance program.

Last month, we discussed risk management basics that can be applied to life science corporate compliance programs to help manage risk.<sup>3</sup> There we noted that one of the key factors of success to assess and mitigate compliance risks is the ability to analyze data. This article extends that discussion and analyzes the critical role of data analytics throughout the Risk Assessment & Management Plan (“RAMP”) process and how compliance professionals can leverage analytics to achieve success.

### Big Data Is Becoming Big

The 21st century is marked with exponential advancement in machines, automation, and artificial intelligence. With the growth of technology, data is being generated at a pace the history has not experienced before.

Not only is the sheer volume growing, but so too is the variety of data—from wearable devices that track heart rates day and night, to sensors that constantly feedback temperature in milliseconds. Consequently, the term ‘Big Data’ is becoming a household name across industries, which Oracle defines as “larger, more complex data sets, especially from

### THE FIVE “Vs” of BIG DATA

Velocity relates to the fast speed at which data is growing

The volume describes the large size of data being generated and analyzed

Variety is about the diversity of the data sources

The value represents the insights Big Data brings to the table

Veracity speaks to the accuracy and precision of the data being analyzed

new data sources.”<sup>4</sup> There are five “Vs” that capture the characteristics of Big Data: velocity, volume, variety, value, and veracity.<sup>5</sup> The table outlines what each of these characteristics relates to.

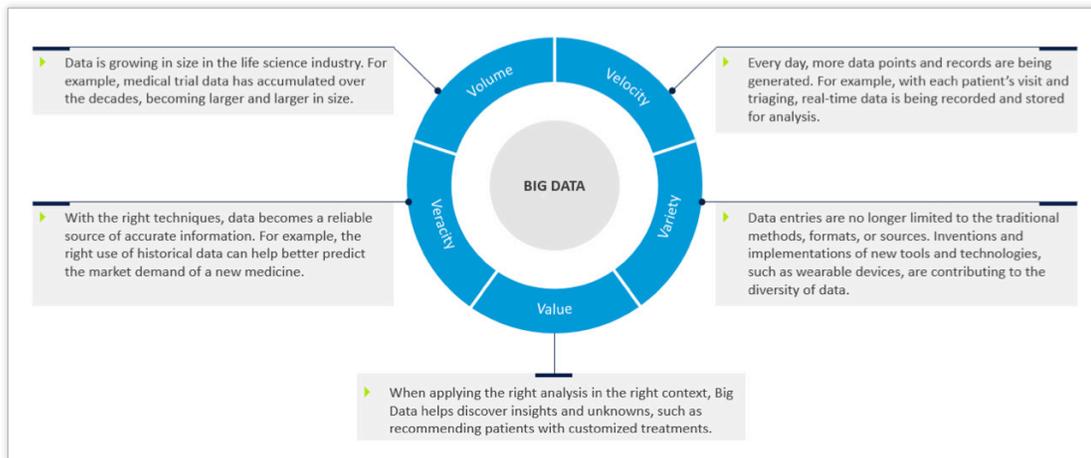
When the correct data analysis techniques are employed in the right context, Big Data brings value by discovering new insights with accuracy and reliability.<sup>6</sup> What, then, does this mean for life science companies? Figure 1 more precisely outlines the five “V”s of Big Data in the context of life sciences.

### Data Analytics in Life Science Compliance

The promise of Big Data and the insights it can bring has triggered a race across industries to develop analytics to extract the value from Big Data fully. The volume, velocity, and variety of data create an ever-growing ocean of information, consisting of both valid signals and invalid noise. The dual limits of resources and time serve to create a demand for more efficient and effective methods to dive into the ocean quickly and filter out the valuable and relevant information (or “signals”) from the rest of the population (or “noise”).

Data analytics helps researchers and companies process Big Data systematically on a mass scale and real-time basis, boiling it down to the essential information desired. Life

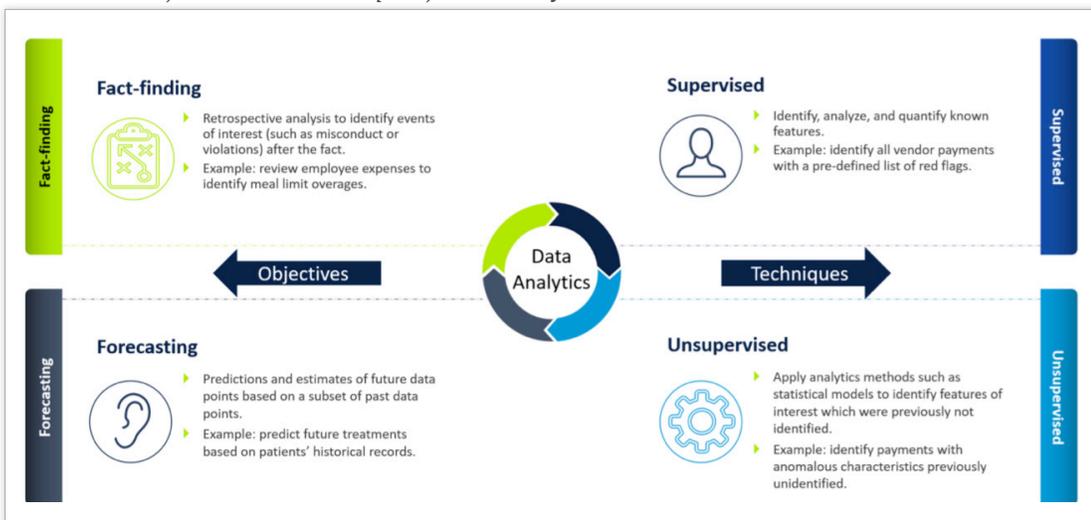
**FIGURE 1: Big Data And 5 V's In Life Sciences**



such applications in other parts of life sciences, such as using a patient's medical history data to predict future treatment plans.

However, once the objective is defined, compliance functions may realize that there are several different analytics techniques that can be applied to achieve the objective. In general, data analytics techniques can be roughly divided into the following two categories:

**FIGURE 2: Objectives and Technique of Data Analytics**



**Supervised:** analytics is used to identify, analyze, or quantify a set of known features and characteristics within the data. For example, compliance can use data analytics to identify vendor spend above a specified limit to determine potential policy violations.

science compliance functions already have begun applying data analytics to achieve two important objectives:

**Fact-finding:** Retrospective analyses to identify misconduct or policy violations after-the-fact. Meal limit overages, exorbitant expenses involving health care professionals ("HCP"), speaker program sign in sheets, etc. are just a few examples of retrospective reviews helping identify non-compliant behaviors.

**Forecasting:** Based on the retrospective analyses, compliance functions can review trends to improve monitoring plans potentially.

While the fact-finding analyses constitute the majority of compliance-related analytics, the power of data analytics also lies in predicting the unknown based on known information. This is the essence of the signal detection process involving Serious Adverse Events. Therefore, there are many

**Unsupervised:** in a lot of cases, it is unclear what is unknown. Unsupervised analytics can help lead into directions not previously thought of. Continuing with our vendor spend example, rather than analyzing vendor spend above a specific dollar amount, an unsupervised model can be utilized to anomalous flag behavior, such a certain frequency of payments, not previously known but also potentially posing risks.

Figure 2 summarizes both the objectives and techniques of data analytics, along with some examples.

## Data Analytics in the RAMP Program

How can the RAMP program, specifically, be integrated with data analytics for a successful outcome? In Part 1, we spent considerable time discussing the application of the key process steps of RAMP to life sciences compliance. In the next several sections, we explain how to integrate analytics

into each of the key process steps of RAMP to ensure effectiveness and efficiency.

### *Setting up the RAMP Program: Good Beginning is Half the Task*

The 5 “V”s of Big Data represents not only the power of Big Data but also the challenges. At the initial setup phase of the RAMP program, effective data management needs to be established to accommodate the velocity, volume, and variety and ensure the value and veracity of Big Data. Other technical aspects include data infrastructure (such as what databases to use), systems integration, and appropriate skillsets (such as data mining, visualizations, modeling, etc.).

Even more important than the technical aspects, the data user needs to understand the core compliance matters and specific business practices. To bridge the gap, cross-department collaboration is required in most cases. For example, compliance, IT, and analytics teams will need to work closely together to integrate subject expertise and skillsets. Sometimes, companies might need to look for external help as well. Figure 3 illustrates the different aspects and considerations to be evaluated during the setup stage of the RAMP program.

### *RAMP Process: Risk Identification*

As discussed in the first article, during the risk identification process, information from various inputs is considered to develop a list of compliance risks and threats. It is important to review the various inputs using data analytics to identify both risks that are known to the stakeholders, as well as risks that may not be obvious. Using unsupervised analysis, as mentioned in the previous section, additional indicators or characteristics may be uncovered and added to the list of identified risks. Additionally, both structured (such as expense data) and unstructured data (such as emails) could provide valuable insights for risk identification. For example, performing unstructured data analysis on comments from email review can generate keywords and sentiments to reflect potential risk behaviors.

### *RAMP Process: Risk Assessment*

Quantitative and qualitative assessments can help compliance professionals prioritize and profile identified risks. At this stage, data are a very powerful source of insight to quantify, rank objectively, and assess the impact and likelihood of certain risks. Forecasts may be helpful in

further understanding the economic and business impact in multiple potential scenarios.

Depending on the identified risks and inputs, a single risk could be examined across multiple inputs to help determine if the behavior is an isolated event, or if a more systemic issue is at hand. For example, examining expense data may show a commercial sales representative spent more than the pre-determined limit for a speaker program meal. While this instance may not be considered ‘high risk’, questions around frequency of over-spend, including timing (e.g., is this occurring immediately prior to a product launch?), sales team region, other common spending patterns, etc. can all be analyzed to determine if the sales representative needs coaching or if a wider investigation needs to be triggered. Oftentimes, there are many different aspects to a specific risk under evaluation. Therefore, it is helpful to assign weights to the different aspects to generate a summarized overall risk score to simplify the assessment.

### *RAMP Process: Risk Mitigation and Monitoring*

Once the corresponding risk mitigation methods are identified, data analysis plays a big role in testing and monitoring the results of risk mitigation. Data visualization (e.g., Tableau dashboards) is a helpful and popular tool to monitor, analyze, and communicate such results. Using visualizations, compliance professionals can quickly set up a baseline of patterns and analyze mitigation results against the baseline to evaluate the effectiveness of risk mitigation

**FIGURE 3:** *Considerations of Successful Data Analytics Applied to RAMP*



methods. With the proper setup and a robust data set, real-time data analysis can be conducted on a per-second basis, constantly refreshed in the visualizations, and providing the most up-to-date information to compliance professionals. Alerts and notifications can be established to inform stakeholders of any significant events of interest automatically. However, it is important to configure alerts and notifications such that they don't overwhelm the recipients.

It also is worth mentioning that conclusions and findings from the mitigation and monitoring process should iteratively inform the previous steps of the RAMP process. For example, additional risks might be identified during the monitoring step, or the effective mitigation could de-prioritize a certain risk. In these cases, the risk identification and assessment processes need to be re-visited. Externally, rapid changes in regulations and technology innovations demand that an effective RAMP program be able to evolve and adapt on a continuous basis.

## Conclusions

Big Data is not just a buzz word anymore. It is both an opportunity and an unavoidable trend. However, where it is ignored, it constitutes a compliance risk. Nevertheless, there are still many challenges and limitations facing compliance professionals when using data analytics.

One of the biggest challenges is the quality and usability of data, or "garbage in, garbage out." Missing data, erroneous outliers, and heterogeneous data formats are among the challenges. Many times, a lot of effort and resources are required to cleanse and prepare data for analytics, leaving little time for the actual analytics and interpretation of the data. We clearly saw that in the early days of Open Payments reporting. However, as more and more technologies are developed, the process of data analytics is getting more streamlined and providing even more value to various applications such as life science compliance.

## GETTING STARTED

To help you get started with implementing a data-driven RAMP process (or to enhance an existing one), we suggest you:

- Review current situation.
  - Review your available data and understand what is ready for analysis.
  - Understand the systems where data resides and the available tools for performing analysis.
  - Assess the talent and skillsets amongst the team, and focus on both technical skills and subject expertise in compliance
- Identify a desired outcome.
  - Define your objectives for applying RAMP.
  - Design metrics to measure the success of RAMP.
- Identify and implement measures to achieve the desired outcome based on the current situation.
  - Consider improving and investing in additional systems and tools to access more data with increased efficiency.
  - Look both internally and externally to bring in more talents.
  - Gain support from leadership and other important stakeholders.

## References

- 1 Ms. Bi is a Manager at Forensic Risk Alliance (FRA). FRA provides multi-jurisdictional expertise in financial and electronic forensics to help companies manage risks in an increasingly regulated business climate. [www.forensicrisk.com](http://www.forensicrisk.com)
- 2 Dr. McVey is also an Editorial Board Member for the Policy & Medicine Compliance Update.
- 3 See J. McVey, S. Whitelaw, Are Life Science Companies Truly Managing Risks? Risk Management Basics, 5.4 POLICY & MEDICINE COMPLIANCE UPDATE 1 (2019).
- 4 What Is Big Data, Oracle, <https://www.oracle.com/big-data/guide/what-is-big-data.html>
- 5 The 5 Vs of Big Data, IBM, <https://www.ibm.com/blogs/watson-health/the-5-vs-of-big-data/>
- 6 The corollary also is true. When the correct techniques are not employed, the value of Big Data can go unrealized.
- 7 For example, variations of the same patient's name could exist across data sources.



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