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Data analytics in life sciences

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Q&A:

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THE PANELLISTS

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Corey Dunbar is a principal with BDO's forensics practice and the leader of the data forensics practice. He specialises in data analytics pertaining to the detection of fraud, bribery, corruption, compliance risks and other forms of nefarious activity occurring within accounting, financial and communicational data. He also specialises in the operations and technology enablement of compliance programmes.

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As a managing director in the governance, risk and compliance practice, Jeff Lawton leads the data strategy & governance practice area, relying on over 25 years of experience helping organisations drive transformation and business value by solving data-related challenges, elevating data management maturity and promoting data literacy.

FW: Could you provide an overview of the extent to which the life sciences industry utilises data analytics across day-to-day operations? How has the appetite to deploy this technology increased in recent years?

Dunbar: The use of data analytics in the life sciences industry is prolific, not only within the research and commercial functions of a business but also often within risk management functions such as legal and compliance. The advent of data analytics and technology within risk management began nearly a decade ago, driven largely by the regulatory environments in which these organisations operate, coupled with the increasing expectation of enforcement agencies such as the Office of Inspector General (OIG) and the US Department of Justice (DOJ) that companies will embed these capabilities within risk identification and mitigation efforts. As companies continue to invest in digital transformation and innovation, it is imperative that these investments reach the increasingly important lines of defence within life sciences companies.

FW: What kind of benefits does data analytics offer the life sciences industry? To what areas and processes is it being applied?

Dunbar: Life sciences organisations operating with an increased amount of risk are making the most use of data analytics. To keep a finger on the pulse, risk management functions must aggregate data from a variety of commercial activities – medical education events, sampling practices, patient support programmes, third-party payments, sell-in and sell-out data, email and other forms of communication with end customers and patients – to get a full picture of their employees' and third parties' behaviour. Life sciences organisations also use analytics for trial data and longitudinal data to detect trends and insights into complications and other side effects. Simply put, the volume in which these activities occur, coupled with the variety of data sets

to be monitored, creates a real challenge for risk identification, mitigation and tracking. Attempting to adequately monitor and react to risk within these business functions is nearly impossible without the use of data analytics and other technologies.

FW: In the regulatory sphere, in what ways can data analytics assist life sciences companies to manage the risks they face as well as meet their compliance obligations?

Dunbar: The DOJ has issued several publications on this topic, elucidating its expectation that companies leverage data and analytics to inform their auditing and monitoring practices, allocate resources appropriately across their organisation, maintain visibility into their use of third parties and track remediation items to completion. A look at the last decade of settlements that led to corporate integrity agreements or deferred prosecution agreements reveals that a lack of visibility into sales functions and third parties is almost always at the core of these matters – risks that could have been mitigated with the use of data analytics in monitoring efforts. Enforcement agencies want to understand how risk is identified and, equally as important, what companies do in response. The use of technology to support operational workflows, specifically remediation tracking, provides quantifiable and defensible data that are necessary for life sciences companies to demonstrate how they accomplish this within their organisations.

FW: In your experience, what are some of the key challenges facing life sciences companies when it comes to harnessing and unlocking the full potential of data analytics, and integrating these processes seamlessly with existing systems?

Lawton: Life sciences companies, which often grow through acquisition, are some of the most diverse and decentralised organisations. This reality manifests itself in day to day operations and the underlying data they create. As a result, wrangling data can present challenges for businesses that lack the technical acumen to adequately define their requirements, as they will be overreliant on IT resources who may not fully understand their needs. Because life sciences companies do not always have the data they need, they often purchase, trade or exchange data sets with

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third parties. When that exchange occurs between parties located in different states or countries, a host of data privacy laws can come into effect. IT resources within the risk management function, or an external provider with data analytics and technology implementation skills, can be a tremendous asset. These resources can translate business needs into technical requirements, offering a more efficient and direct path to integration.

FW: With more life sciences companies turning to data analytics, what steps do they need to take to manage related privacy considerations when using this technology?

Lawton: Life sciences firms can manage data privacy risks by understanding the full scope of their compliance needs across jurisdictions, assessing their compliance posture and remediating gaps as quickly as possible. Life sciences firms need to know what data assets they have, where they are located, and which of those assets have which types of personal data. Life sciences firms must also document which business processes create or consume personal data, the reasons for using that personal data and how they protect it. These firms need to understand the record-keeping requirements of their jurisdictions, preserving records until their minimum limits are reached and deleting them when their maximum limits are reached. Using privacy by design techniques will allow life sciences firms to create and update their data protection posture in line with changing regulations.

FW: What essential advice would you offer to life sciences companies on leveraging data analytics and associated technologies to drive business innovation, improve efficiency and provide the best return on investment?

Dunbar: If a company has not already started to invest, it should get to it. The life sciences industry is one of the most regulated and targeted industries for enforcement agencies. Maintaining an effective compliance programme is becoming increasingly difficult without data analytics capabilities. Failure to demonstrate compliance can result in significant fines and lengthy settlement agreements that lead to even more loss of profit over time. Companies that have invested in and evolved their data analytics capabilities have a resource to help demonstrate that unwanted behaviour is truly anomalous, not pervasive in their organisation. You need to demonstrate your risk management efforts are risk-based, repeatable and defensible – or else risk the consequences. When selecting analytics technologies, companies must make sure to cover all business needs, but keep the overall number of tools small to limit costs and training needs. This means all tools must be selected with intention, not to chase a fad or trend.

FW: Do you expect to see increased uptake of data analytics across the life sciences industry in the months and years ahead? What further benefits, advantages and opportunities can we expect from this technology?

Lawton: As companies invest in data analytics capabilities to drive up their revenue and profit margins, they need to proportionately invest in their risk management functions. The use of generative artificial intelligence (GenAI) will be something to keep an eye on, as life sciences organisations integrate these capabilities to provide better services to their customers and patients. When it comes to risk management, ensuring the proper guard rails are in place to define proper use of these technologies will be half the battle. The other half will be integrating them at the same capacity to adequately monitor their use. ■

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