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Teva Pharmaceutical Reengineers Compliance With Data Analytics

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Teva Pharmaceutical Reengineers Compliance With Data Analytics

Complying with anti-corruption regulations has always been a challenge for large, multinational enterprises conducting business in many different markets. Over the past 15 years, enforcement of the U.S. Foreign Corrupt Practices Act (FCPA) has increased dramatically, from just a handful of cases in the early 2000s to a high of 58 enforcement actions taken by U.S. regulators in 2016 and 49 in 2019.¹ Third-party risk is particularly problematic for multinationals. According to the FPCA Clearinghouse, most FCPA violations (80% to 100% in any given year) involve bribery schemes with third-party intermediaries. (For more on the FPCA, see “The Foreign Corrupt Practices Act and Third-Party Due Diligence, Explained,” p. 3.)

Meanwhile, anti-corruption efforts outside the United States have intensified as more countries have begun to enact new laws or strengthen existing ones. Multijurisdictional cooperation in investigating bribery and corruption is becoming more robust.

However, all this increased attention on and enforcement of anti-corruption laws and regulations seems to be having little effect. According to EY’s 2018 Global Fraud Survey, instances of fraud and corruption have not decreased: 38% of respondents said bribery and corruption was frequent and widespread in their country, a number that has not changed since 2012. More than 1 in 10 companies also reported experiencing significant fraud in the past two years.

Obviously, companies need better ways of identifying and managing these risks. This case study examines an approach developed by Teva Pharmaceutical Industries Ltd. and its consulting partner. The system uses data analytics, a clearly defined process, and an innovative and technology-enabled workflow designed to help the company identify and manage third-party risk more effectively and efficiently. Going forward, Teva intends to further enable this workflow through the use of advanced technologies such as AI to enhance risk mitigation efforts.

Background: A Pharmaceutical Giant Hits Rough Waters

Teva was launched by three pharmacists in Jerusalem in 1901. Today, it is a global leader in generic and specialty medicines. The company manufactures more than 3,500 medicines at more than 70 facilities around the world. Still headquartered in Jerusalem, Teva employs 43,000 people and reported revenues of \$19 billion in 2018.

¹ Foreign Corrupt Practices Act Clearinghouse,” Stanford Law School, accessed June 10, 2020, <http://fcpa.stanford.edu>.

In 2012, Teva began investigating possible FCPA violations after receiving subpoenas from the U.S. Securities and Exchange Commission and the Department of Justice. In December 2016, the company reached a settlement with both government agencies over violations involving bribes paid to government officials in Russia, Mexico, and Ukraine between 2007 and 2013. The company paid a penalty of \$519 million and entered into a deferred prosecution agreement (DPA) with the DOJ. Under the terms of the DPA, the DOJ would dismiss the charges if Teva met certain conditions. Among them:

- Continue to cooperate with the DOJ.
- Retain an independent compliance monitor for three years.
- Improve compliance by establishing a system to better monitor more transactions.
- Enhance the company's dedicated third-party due-diligence program.
- Bolster the independence of the company's control functions.

In particular, Teva needed to identify which of its more than 500,000 vendors and customers — including agents, consultants, distributors, suppliers, vendors, and any other entity or individual facilitating or involved in any transaction with government officials or agencies, including health care entities (which are sometimes operated by governments) — could potentially introduce FCPA risks, and ensure that appropriate due diligence was performed before they were hired or paid.

Focus on Improving Third-Party Due Diligence

More than a year before the 2016 settlement, Teva hired Lori Queisser as senior vice president and global chief compliance officer to improve its overall compliance program. Queisser has more than 30 years of experience in compliance at pharmaceutical companies, including Eli Lilly and Schering-Plough.

Queisser says that when she joined Teva, she encountered a “spaghetti bowl” of processes and systems across procurement and finance. The company had grown explosively, primarily through acquisitions, over the previous two decades. Since 1999, it had acquired a dozen other companies and inherited their legacy systems. (See “Timeline of Teva Acquisitions,” p. 5.) Most of the systems were old — some decades old. Some processes were still done manually, on paper.

While there were many different types of systems, Teva followed the same basic process for every third-party representative (TPR) regardless of level of risk, type of business, or business location:

- A business sponsor nominated a new TPR by sending a form to the compliance department.
- Compliance sent a questionnaire to the TPR.
- After the TPR returned the completed questionnaire, Teva would decide whether to investigate the party.
- If an investigation was conducted, the compliance department reviewed the report and its recommendations.
- A local due-diligence committee reviewed the report and recommendations.
- The due-diligence committee either approved, approved with conditions, or denied the TPR.

This process could take weeks to months. And Teva was processing 1,800 to 2,000 TPRs every year.

This time-consuming, expensive, and ultimately inefficient process was frustrating for business sponsors and for Queisser. She thought there had to be a better way.

“Honestly, we weren’t confident in the results of the process,” she says. “We were spending millions and millions of dollars on third-party due diligence, as does every U.S.-listed public company, but we weren’t reducing our risk. I was not going to continue to spend a lot of money and continue to get results in which I had no confidence.”

She wondered whether the process could be streamlined through the use of data, technology, and analytics, and she began talking with potential consulting partners about the possibilities. “I told them I wanted a game-changer,” she says. “I wanted to make a disruptive move in this space.” Could they design a due-diligence system that was proactive rather than reactive? Why not build a worldwide database of already vetted partners that business units could choose from? Businesses would jump at the chance to use something like that if it meant a much faster and better process, she believed.

“There’s an old adage in organizational change management,” Queisser says. “You try to make a desired behavior easy and rewarding. People will do things that are easy and rewarding.” Especially if the old method is difficult and painful.

Queisser hired a consultant that had both innovative ideas and was willing to partner to develop such a system. The partner was willing to make a significant investment in what was essentially an experiment, she says. “We didn’t know whether it was going to work. And I needed it quickly because I had this external monitor breathing down my neck, and this was the biggest gap in my compliance program.”

But Teva’s aspirations went beyond meeting legal requirements. Its officially stated goal was to “build the best and most respected global compliance program in the industry — a

The Foreign Corrupt Practices Act and Third-Party Due Diligence, Explained

Since its passage in 1977, the Foreign Corrupt Practices Act (FCPA) has prohibited U.S. companies and individuals from paying bribes to foreign officials in furtherance of a business deal. It applies to any actions anywhere in the world by publicly traded companies, including their directors, officers, shareholders, agents, and employees. This also includes third parties such as agents, consultants, distributors, and joint venture partners. Therefore, the use of proxies does not shield a company or individual from culpability. The Securities and Exchange Commission and the Department of Justice jointly enforce the FCPA.

Here are the guiding principles for FCPA third-party due-diligence compliance published by U.S. regulators:

- **Know the qualifications and associations of third-party partners, including their business reputations and relationships, if any, with foreign officials.** The degree of scrutiny should increase as red flags surface.
- **Understand the business rationale for including the third party in the transaction.** Note the timing of the third party’s introduction to the business. Make sure that contracts specifically describe the services the party will perform and the payment terms. Know how those payment terms compare to typical terms in that industry and country. Confirm and document that the third party is actually performing the work for which it is being paid and that its compensation is commensurate with the work being provided.
- **Conduct ongoing monitoring of third-party relationships.** This may include updating due diligence periodically, exercising audit rights, providing periodic training, and requesting annual compliance certifications by the third party.

program that works in partnership with the business to prevent issues.” That meant business sponsors needed to understand that compliance was a part of their responsibility and that they would be held accountable for their decisions. Accordingly, the compliance department needed to provide the business with the right tools, resources, policies, and training to facilitate the right decisions. In third-party due diligence, specifically, the goal was to transform Teva’s program into a system that other companies would strive to replicate, says Tali Guy, Teva’s vice president of compliance and third-party due diligence, and the company’s global privacy officer.

Teva’s partner built a database that combined information from public sources such as regulatory filings, court rulings, ownership records, and news reports. It also drew from proprietary data on politically exposed persons as well as officers and major shareholders of third parties. (See “Teva’s Information Sources,” p. 10.) Then Teva and the consultant developed business rules that would feed algorithms to crunch the data and calculate a risk score and level for each TPR: low, medium, or high.

The rules accounted for Teva’s risk tolerance, its existing knowledge of markets, and the types of services it used. The business rules treated different parts of the world differently. For example, because the level of corruption is relatively low in Western Europe (based on Transparency International’s Corruption Perception Index) and the level of transparency is high, the system would allow Western European vendors with a low risk ranking to be engaged without requiring a questionnaire, investigation, or deliberation by a due-diligence committee. In international markets, however, where there tend to be higher levels of corruption and less transparency (and fewer sources of reliable information), Teva’s rules dictated that even low-risk entities would still require due-diligence committee input. Because these committees are local, they can provide vital boots-on-the-ground knowledge.

Teva ran pilots to test how the pre-screening tool performed compared with the company’s old process. In the pilots, the database not only identified the same risks for TPRs that Teva had previously, but it also identified 40 additional third parties that had risks of which Teva was unaware. For those third parties, the tool identified low-risk TPRs that provided similar services, giving Teva more options.

In short, the pilots demonstrated that the pre-screening tool could find and assess risk faster and on more parties than Teva was formerly capable of doing. In one test, the system assessed risk on twice as many third parties in 30 days than Teva had assessed over eight months with its old approach.

Finding the Right Control Points

The next step for Teva was figuring out where and how to integrate the pre-screening tool into the company’s business processes.

A team of representatives from compliance, procurement, finance, legal, and IT examined the entire process from procurement through purchase-to-payment (P2P) to determine the best places to embed controls, says Elly Bisschops, Teva’s head of global procurement operations. In the process, the company made a surprising discovery: Teva actually had 35 different P2P processes. What’s more, the same P2P process was sometimes implemented differently in different locations. When that was factored in, Teva counted 102 different P2P “implementation units,” says Bisschops.

This complicated an already complex project, but putting the process under a microscope “forced us to look at things from the ground up rather than the top down,” says Deborah Griffin, senior vice president and chief accounting officer at Teva. “That’s where a lot of the ‘aha’ moments came from.”

Teva realized, for example, that it needed to set an additional goal for the project: to ensure that its global procurement policies and best practices were followed consistently around the world, says Bisschops.

If there had been more time, Teva’s multiple P2P systems could have been standardized and integrated, but “we couldn’t wait to deploy a common system around the world,” says Griffin. “That would take too long, and we were on the clock with the deferred prosecution agreement monitor.” The monitor had the responsibility of approving and certifying Teva’s improvements by the end of 2019 — the three-year DPA period.

“Our procurement strategy had been to integrate the biggest countries first,” says Bisschops. “But this project made us realize we had to speed up the integration of some smaller, high-risk countries into our central operations. We had not realized how immature the processes were in some of these countries.”

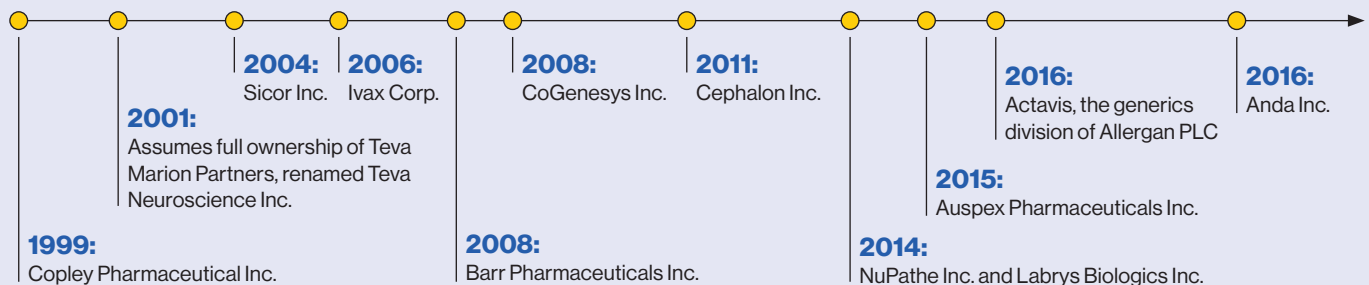
Teva had to reprioritize which countries’ processes would be centralized into global hubs, Bisschops says. The main hub, in Croatia, served Latin America, the United States, Canada, and Europe. A second hub, in India, was due to expand to include other countries in the Asia-Pacific region.

In 2019, Teva was in the process of rolling out SAP Ariba as its global indirect procurement system, but only 13 countries were using it at that time. Other locations used their own systems. In locations without any automated systems, Teva implemented a SharePoint solution.

Timeline of Teva Acquisitions

Since 1999, Teva has acquired the following companies:

1999-2016



The cross-functional team designed the workflow that guides business users through the control process, routes the appropriate information to the appropriate people, provides transparency to users, and creates and retains an audit trail.

The system automates the process based on Teva's business rules at key decision points. If a user wants to engage a European third party with a low risk ranking, her request is automatically routed to the appropriate party to issue a purchase order, rather than having to go through steps required for riskier entities. For medium- or high-risk parties, the pre-screening tool automatically delivers and ingests the documentation required. For instance, if a user wants to hire a medium-risk party in an international market, the system automatically sends a questionnaire and appropriate privacy notice to that third party, in the appropriate language.

The system presents one workflow to all users despite the different technologies deployed across the company, masking the fact that the controls are implemented differently depending on the system. Teva's various P2P systems feed data into the pre-screening tool eliminating manual steps previously required to move information. "Our partner figured out a way to build a front end that walked users through these checks. That's where the magic occurred," says Queisser. "It meant that cash wouldn't flow if the right work had not been done. That was very, very important to us and to our external monitor."

Challenges: Change Management and Organizational Complexity

The team encountered several challenges along the way, including (but not limited to) managing multiple changes simultaneously, validating and sharpening the business rules, aligning the system with multiple disciplines in the company, gaining the confidence of management and users, and doing all of that — and more — under the pressure of the DPA.

The biggest challenge was change management. Not only was this a massive undertaking, but implementation and training differed from one place to another. Remember, Teva had identified 102 different implementation units across 60 countries.

"Sometimes they used the same process, but it was in a different country, so there was a different set of changes to manage," says Griffin. "The technology might have seemed easy because you'd already implemented it someplace else, but you still had to go in and train the users and get everybody aligned on the new process." The team developed training materials and user guides in 20 languages, adapting them to cultural sensibilities and conventions in different parts of the world.



"We had to work together as one team, leverage the capabilities and expertise we found in other areas of the company, bring everyone to the table, establish clear priorities, and manage it all very closely to make sure all the pieces came together and we met deadlines."

TALI GUY, Vice President of Compliance and Third-Party Due Diligence, and Global Privacy Officer

On top of that, they trained while implementing and tweaking the system. “We were building the plane while it was in the air,” explains Griffin. As of November 2019, 16,000 people — 98% of Teva’s target — had been trained.

Another huge challenge was designing and perfecting the business rules, says Queisser. Teva couldn’t validate the rules using previous due diligence because the former methods were not effective. It could compare the pre-screening tool results to the results of the previous method, but that was not good enough.

“We had to get confident that the results [of the new business rules] made sense, which was hard to do because we really didn’t know what the results should be,” Queisser says.

However, as a compliance veteran, Queisser had deep knowledge about corruption levels in various countries. If results for a certain country came back with very few high-risk TPRs, “I’d say there’s no way this country has only two high-risk TPRs,” she says. In that case, Teva would tweak the system and try again. In one country, Queisser personally knew of two high-risk distributors. When they both showed up as high risk in the tool, she knew the database was “directionally correct.”

Getting and maintaining alignment, as well as dividing tasks among many groups — compliance, procurement, finance, IT, and the outside consultant — was another challenge. “We had to work together as one team, leverage the capabilities and expertise we found in other areas of the company, bring everyone to the table, establish clear priorities, and manage it all very closely to make sure all the pieces came together and we met deadlines,” says Guy.

And at every step of the way, they had to communicate with the monitor, which, under the terms of the DPA, had the legal responsibility of assessing and certifying that Teva’s compliance program was “reasonably designed and implemented to prevent and detect violations of the anti-corruption laws.”

“We had to make sure the monitor approved before we moved ahead,” Griffin says. “We were constantly interfacing with them, keeping them up to date.”

The company also was confronting significant financial pressures. In 2017, Teva’s then-new CEO Kåre Schultz had launched a restructuring program to cut costs by \$3 billion.

“Every part of the organization was stretched pretty thin,” says Griffin. “So, the first response to something new was to say, ‘It’s not my job; I don’t have the staffing.’ But we set the tone from the get-go that this was important to Teva. We had to do it.”

Finally, and most important, Teva had to gain the trust of the business users. If business users were going to change how they did things, they had to be convinced that those changes were worth making. For Queisser, the initial indications are good. “People are using [the new system],” she says. “That’s because it presents a better way to do the right thing. It provides users with a system that’s easy to use, gives them visibility into a previously opaque process, and helps them onboard TPRs more quickly.”



There's no question that the system is saving substantial amounts of time, says Katie Gitas, Teva's Senior Director of Compliance. Gaining third-party representative approval has dropped from a period of weeks or months to as little as a few hours to two days. That benefit has freed up the compliance team to focus on examining higher-risk parties.

KATIE GITAS, Senior Director of Compliance

One demonstration that went a long way in selling the system to the business was the second phase of an ongoing reconciliation effort. Reconciliation meant identifying all Teva customers and vendors worldwide and then checking to see whether they met the definition of a TPR. Whenever one did, Teva had to make sure the proper due diligence had been performed, and if it had not, do it. The first phase, which covered 10 European countries, was done manually. "We went through hundreds of thousands of entities, examining vendors one by one," says Queisser. It took over a year.

In the second phase, they used the pre-screening tool. The business rules in the system meant it automatically assigned a risk level to all potential third parties and identified which entities were low risk and, therefore, didn't require further due-diligence. That reduced everyone's workload considerably. The company reconciled entities from 26 countries in less than five months.

"That really helped us to gain the trust of management and the trust of the business sponsors that would be using the tool on a daily basis," says Guy. "It's a win-win situation for the business because when sponsors engage with low-risk parties, they get an expedited process. If there is a specific [higher-risk] third party they need because it has specific qualifications, then it will require more time, but the sponsors know that compliance will support them and help manage that."

Results and Benefits

Today, the pre-screening tool contains approximately 25 million records in more than 45 different service categories across 60 geographies. The system can also provide prescreening for entities not in that universe by tapping into proprietary databases. This expands the potential pool to more than 300 million entities across more than 600 service types.

More than 1,500 Teva employees now use the system. While it's too early for definitive proof that the system is driving behavioral change, Teva believes that given the chance to choose a low-risk TPR rather than one with a medium or high risk rating, more people will choose lower-risk TPRs than before, says Katie Gitas, senior director of compliance. What is certain, and quantifiable, she says, is that the system is saving substantial amounts of time. Gaining TPR approval has dropped from a period of weeks or months to as little as a few hours to two days. That benefit has freed up the compliance team to focus on examining higher-risk parties.

The well-defined workflow clarifies the required steps, shining a light onto the process. Before, "it was like a black hole," says Guy. After nominating a TPR, business sponsors received no information until it was either approved or denied. They could call the compliance department for updates, "but there was nothing the business sponsor could do themselves to

find the information. Now, they can go into the system at any point and see exactly where their request is. They can generate a report, for example, that displays all the third parties they have in process.”

The pre-screening tool manages much of the process. If Teva has not received a complete questionnaire within a certain amount of time, the system automatically sends a reminder to the TPR and the business sponsor. If it receives no response within 90 days, the system closes the case and denies the request. This not only saves the compliance team time and resources, but it also prevents situations that linger a long time, which could tempt people to try to circumvent controls. And it makes it easy to manage, review, and analyze requests. Dashboards enable users to see all TPRs and their risk levels. Users can sort TPRs by market, risk level, or service category. They can see when the risk profile of a TPR changes and when due-diligence renewals are coming up. Different views and reports are available to different types of users. Business sponsors can generate reports on their third-party vendors. Local compliance officers can see the broad view of what’s happening in their locale. Executives can look at worldwide views.

An unexpected benefit of the project is that now Teva has a vetted database of vendors and customers with which it does business. The only ones that require additional attention and due diligence are the ones that serve as intermediaries to government officials or the health care entities through which some governments work. “We’re still paying them for products and services,” says Queisser. “It’s nice to know that they’re good vendors and don’t have any red flags.”

There are still areas of the world where Teva reverts to the old, slower process of investigating TPRs. In certain high-risk international markets, there just isn’t much data available, notes Queisser. But that’s better than having to do every evaluation the old way. In 2020, about 75% of Teva’s TPRs will be prescreened through the tool..

While Teva is currently on track for on-time completion of the DPA, this project has gone way beyond simply meeting its legal obligations. The company is well on its way to meeting its goal of building the best global compliance system in its industry. It now has a framework that gives business users the tools to become accountable for compliance and enables compliance to support them.

“We are cultivating a feeling of accountability for compliance within the business ... so we have the right people, doing the right things, the right way,” says Queisser. By making due diligence an integral part of a clearly defined and automated process, compliance at Teva has become proactive rather than reactive. “I’m finally off my heels and onto my toes,” says Queisser. “We are leaning into [compliance] rather than looking in the rearview mirror.”

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LORI QUEISSER,
Senior Vice President and Global Chief Compliance Officer



Next Steps: Making the System More Intelligent

Teva has plans to make the system even more proactive.

The team is building a back-end detection-control system that will analyze the path of TPRs to identify breakdowns in controls. It might detect, for example, a vendor with an invoice dated before the purchase order date. The results of these analyses will tell Teva where it needs to improve training, update policies, or tweak the system.

Going forward, Teva is exploring adding artificial intelligence to enhance TPR prescreening. The AI would draw on TPR reviews, approvals and denials, and outcomes such as investigation results and audit reports to create a predictive model that could automatically identify attributes that can signify increased risk. Building on that, it would suggest ways to better evaluate potential business relationships.

Beyond that, Teva could adapt the system to monitor and assess other kinds of risk, says Guy, such as detecting counterfeit drugs or ensuring compliance with privacy regulations. “There are many things we can do with this that really support our vision of compliance,” she says.

For now, though, Queisser is keeping her focus on third-party due diligence. “Third-party due diligence is a significant piece of the FCPA, and it’s one of the hardest elements of a compliance program,” Queisser says. “Any U.S.-registered company that has to comply with the FCPA should be looking into this.”

Teva’s Information Sources

- Transparency International's Corruption Perception Index.
- Sanctions lists, including those available from the U.S. Treasury Department's Office of Foreign Assets Control, the European Union, the United Nations, the U.K.'s Office of Financial Sanctions, the U.S. Federal Bureau of Investigation, and the U.S. Department of Commerce's Bureau of Industry and Security.
- Information from enforcement lists and court filings from agencies such as the U.S. Food and Drug Administration, the U.S. Department of Health and Human Services, the U.S. Securities and Exchange Commission, and U.K. Financial Services Authority.
- Profiles from the largest database of politically exposed persons, including family members.
- Government-owned and government-linked corporations and businesses.
- Media reports and other open sources related to bribery, corruption, fraud, other financial or regulatory matters, and narco-trafficking.



Todd Marlin, EY Global Forensic & Integrity Services Technology & Innovation Leader, specializes in advising companies on complex issues surrounding data, security, legal, and compliance risks. He leads an international team with extensive experience in using advanced technologies to develop analytics models.



Kris Curry, EY Americas Forensic & Integrity Services Health Sciences Leader, specializes in assisting companies in identifying solutions that respond to enforcement risk while developing proactive controls to mitigate program vulnerabilities. She has more than 25 years' experience in the life-sciences industry, compliance oversight, and regulation.

SPONSOR'S VIEWPOINT

Data and Analytics Lay the Groundwork for a Modern Compliance Function

Teva Pharmaceutical Industries' success at overhauling its third-party risk management program demonstrates how compliance can be a force for change in an organization. The impressive results Teva achieved by focusing on data and workflow design are relevant to any organization confronting the sometimes dueling challenges of tightening compliance while speeding time to business decisions. In fact, lengthy compliance processes can endanger both business relationships and productivity, without necessarily reducing risk.

Teva's story highlights three key elements for retooling legacy compliance programs that are perceived as bottlenecks to business operations:

- The right data.
- Innovative workflow design.
- The adoption of analytics technologies in risk evaluation.

Assembling the right data for decision-making is foundational to gaining the insights needed in vetting third-party entities for regulatory compliance. It also lays the groundwork to apply advanced analytics and artificial intelligence (AI) to more effectively evaluate the risk involved in a given process.

Teva's journey started with a senior leader with a vision to develop a data-driven compliance function. Under Lori Queisser's leadership, businesses came on board and supported the project team to articulate the vendor base risk profiles and identify the data sources that reveal certain risk characteristics, whether from internal systems or public domains.

A key element of Teva's success is an innovative workflow design that exponentially shortens the third-party due-diligence process, from data collection, cleansing, and analysis to risk ranking and evaluation. The final component: a case management tool that manages workflow tasks from a central dashboard, enhanced by interactive visualizations and audit trails to give compliance leaders access to the information they need to make informed and timely decisions.

Building on the established infrastructure, Teva can further enhance its ability to proactively assess additional risk areas as the organization's business objectives evolve by employing advanced AI technologies such as topic modeling and linguistic analysis. In addition, these technologies can enhance risk insights to contribute to the business planning and decision-making processes. Teva's case has already proved risk insights to be valuable in mitigation efforts. Finally, risk prediction is another area where we see AI increasingly being applied. While it's not yet considered a mature application, the potential is undeniably there. Saying "the sky's the limit" is no exaggeration.

This data- and analytics-driven approach helped Teva lessen the time required to onboard third-party vendors, drive consistency in international markets, and reduce the cost of third-party due diligence. What's more satisfying is knowing that our work together can be easily extended to other compliance programs and, ultimately, lead to a modern data-driven compliance function.

— **Todd Marlin**, EY Global Forensic & Integrity Services Technology & Innovation Leader
 — **Kris Curry**, EY Americas Forensic & Integrity Services Health Sciences Leader