

How is compliance evolving to address emerging risks?

Global Life Sciences
Benchmarking Report 2024



The better the question. The better the answer.
The better the world works.



Building a better
working world

Contents

Methodology	02
1 Introduction: an era of escalating business risks	03
2 Global Life Sciences Benchmarking Report	04
3 Conclusion: maintaining compliance's upward trajectory	22

Methodology

The data for our research was collected in telephone interviews with compliance leaders and digital analytics professionals from nine global life sciences companies between 20 November 2023 and 19 January 2024.

Participants were invited by the EY organization, with Ipsos conducting the interviews. All data is unweighted.

1

Introduction

An era of escalating business risks

Life sciences companies are facing an escalation of risk to their businesses and reputations.

In keeping organizations accountable, regulators continue to introduce new regulations or enhance old ones; both within the sector itself – as with the US Federal Trade Commission's ongoing challenge to "improperly listed" drug-device patents – and industry-wide as with China's cross-border data transfer legislation and the EU's Artificial Intelligence Act.^{1,2,3} Disruptive technologies are creating both challenges, such as ever more sophisticated cyber attacks, and opportunities from efficiency-yielding automation to the innovation potential of artificial intelligence (AI). Yet even these opportunities, if not handled well, can generate further risks. Companies' own corporate activities are also possible risk targets with, for example, consumers, investors and other stakeholders increasingly holding corporations accountable for environmental, social and governance (ESG) failings. In parallel, with many regions still facing economic pressures, the incentive for fraud and corruption remains high – a risk intensified in life sciences companies with more active use of sales incentives.⁴

This challenging environment is increasing the pressure on compliance teams to monitor, identify and remediate new and established risks; all at a time of competing cost pressures and greater expectations of the value the function can provide. To give life sciences companies access to current leading practice, the EY Forensic & Integrity Services team surveyed compliance leaders and data analytics professionals from nine of the sector's leading across the globe businesses to capture how they are countering present and future risks.

The findings show that all surveyed companies are evolving their organization, practices and mindset to strengthen their guard. In doing so, we found common characteristics – such as investments in data analytics to gather insights that can benefit the entire business, and the development of a more collaborative culture. We also identified factors that can help enhance the effectiveness, such as the alignment of across the globe teams behind standardized processes. We found that such evolution is not only helping compliance teams to future-proof their businesses but also elevating the function from business support to business enabler.

¹ "FTC continues to highlight FDA Orange Book patent listings", *Hogan Lovells* website, engage.hoganlovells.com/knowledgeservices/news/ftc-continues-to-highlight-fda-orange-book-patent-listings.

² "New rules adopted for cross-border transfer of data out of China", *Reed Smith* website, reedsmith.com/en/perspectives/2024/03/new-rules-adopted-for-crossborder-transfer-of-data-out-of-China.

³ "Artificial Intelligence Act: MEPs adopt landmark law", *European Parliament* website, europarl.europa.eu/news/en/press-room/20240308IPR19015/artificial-intelligence-act-meps-adopt-landmark-law.

⁴ "Top Sales Compensation Trends for 2024", *Alexander Group* website, alexandergroup.com/insights/life-sciences-top-sales-compensation-trends-for-2024.

2 Global Life Sciences Benchmarking Report

A photograph of a scientist in a white lab coat and safety glasses, holding a test tube with a red liquid. The scientist is in a laboratory setting, with a computer monitor and other laboratory equipment visible in the background. The image is slightly blurred, creating a professional and focused atmosphere.



An evolving role and status

Compliance's role is broadening. The function's traditional job of risk detection and mitigation, with its identification of evolving risks or trends and the sharing of such findings with the business for proactive resolution, is still central. Indeed, 91% of compliance leaders say that gaining new insights on potential risks is a priority. Compliance teams also still focus on ensuring adherence to regulation to maintain licenses to operate and comply with global and local laws, such as the UK's anti-bribery and corruption legislation. And they still manage reputational risk and any resulting share price impact. But, in addition, they are now increasingly receiving requests for – and providing – insights that can potentially both help organizations improve certain processes and controls and assist them in making more informed strategic decisions. One compliance leader neatly sums up this wider, value-added role: "On the one hand, we're trying to keep our business safe. On the other, during the monitoring processes, we're trying to find some process gaps or inefficiencies or ineffective controls, so that we can drive process enhancement."

Life sciences compliance teams at a glance



Verdict on program

Largely mature or fairly mature

Common aim

Greater proactivity

Key recent challenges

- Organizational change
- Resources
- Tech, innovation and data availability

Main 2024 objectives

- New insights on risk
- Adapting to new risks and business changes
- Integrating analytics and AI into monitoring

91% of responses mentioned gaining new insight on potential risks as a priority.

Technology and data analytics are providing compliance with the tools to deliver such insights. Intelligence has the potential to both help organizations manage risks better – one compliance leader talks of the need to “use data analytics to inform your understanding of potential risk” – and to help businesses devise better strategies. Compliance analytics can enable companies to see and contrast trends and themes across the whole organization, with learnings and risk identification being shared with senior leaders and other markets to inform future actions and priorities. Reflecting these possibilities, four out of five (80%) data analytics professionals say data analytics plays a very significant role in their organization’s compliance program.

Having the key to such data-driven insights has elevated the importance and status of the compliance function. One function leader describes, “the shift from being seen as a controlling function, gatekeepers of everything, to being more of a business partner,

aligned and agile with the business objectives. This has been, and is, an ongoing shift and a change for compliance.”

With technology and data analytics offering a route to so much added value, tech is – unsurprisingly – central to compliance leaders’ top three objectives for 2024.

The strategic value that compliance holds is seen in its rise within organizations, with chief ethics and compliance officers playing a key role in executive committees and leadership teams.

To support their expanding role – driving risk mitigation while managing the ever-increasing risk universe and funneling insights back to their businesses – our findings show that compliance teams need key resources. In particular, they require advanced technology and data analytics, including people with the skills to both manage risk and interpret harvested data, and a flexible delivery model and governance system that can adjust continuously and effectively.



An evolving risk landscape

Compliance teams are facing a growing, increasingly complex and constantly evolving range of risks that are testing business resilience. The UK Economic Crime and Corporate Transparency Act introduces a new corporate criminal offense of failing to prevent fraud where the business is deemed to have benefited. Under the act, which is expected to come into force within the next six months, large culpable organizations could face criminal prosecution and unlimited fines. Even if directors were ignorant of the offense, companies could still be found liable, with the only defense being the existence of "reasonable procedures" against fraud.⁵

Fraud has, of course, long been a key risk for business – as backed up by our survey, which shows that compliance leaders see it as one of the top three risks (along with bribery and corruption and data privacy). However, as well as making companies more accountable, the new act potentially widens the definition of fraud. The act's categorizations of what constitutes the offense has been interpreted as applying to "greenwashing," that is "making inaccurate, misleading, or unsubstantiated claims about the sustainability benefits of products and services offered, or about a firm's strategic aspirations and actions." For example, the act cites fraud by false representation and by failing to disclose information, pitfalls a company could lurch into if presenting an over positive picture of their sustainability credentials.⁶ The act's introduction of the new "failure to prevent fraud" liability will by itself exercise compliance teams, and other assurance functions, in ensuring their firms have "reasonable procedures" in place. A potential greenwashing liability will extend them even further; requiring them to move beyond financial metrics to non-financial ones, in aiming to monitor, detect and prevent greenwashing risks.



The potential arena for "misstatement" of sustainability credentials ranges from marketing materials to regulation – including the EU's new Corporate Sustainability Reporting Directive (CSRD), which includes new standards and requirements for companies with principal activities in the EU to disclose information on their ESG impacts and risks.⁷ The continuing challenge from such new regulation is acknowledged in the latest *EY Global Board Risk Survey*, which found that 46% of global board director respondents believe regulatory changes will have a severe impact on their business in the year ahead, up 3% from the previous biannual survey.⁸

⁵ *Failing to prevent fraud: Avoiding corporate criminal liability*, Ernst & Young LLP, 2023.

⁶ *Failure to prevent and how it could impact greenwashing*, EYGM Limited, 2024.

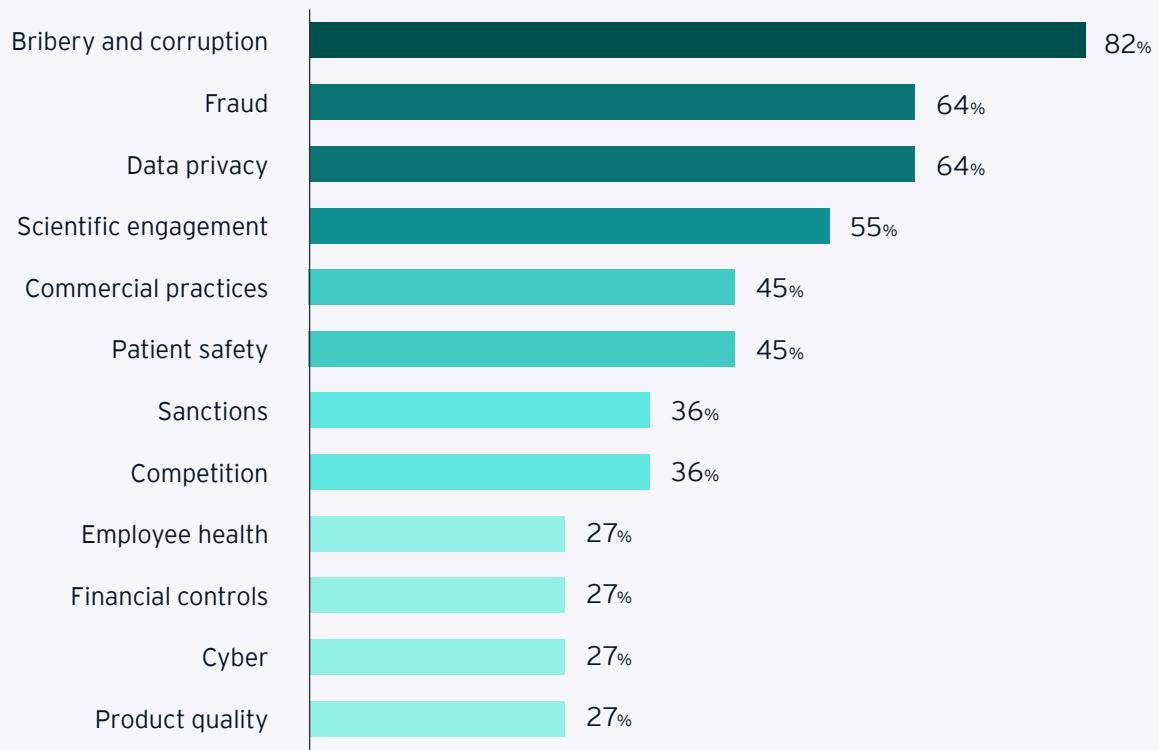
⁷ "Why CSRD is a game changer for sustainability reporting", *EY website*, ey.com/en_fi/consulting/why-csrd-is-a-game-changer-for-sustainability-reporting.

⁸ "What if the difference between adversity and advantage is a resilient board?" *EY website*, ey.com/en_us/global-board-risk-survey/what-if-the-difference-between-adversity-and-advantage-is-a-resilient-board.

Our research shows that, alongside more traditional risks, the relatively recent risk of cyber attacks is now a constant. Advanced technology means this risk is changing rapidly. Global insurer Allianz reports: "Threat actors are already using AI-powered language models

like Generative AI to write code. Generative AI can help less proficient threat actors create new strains and variations of existing ransomware, potentially increasing the number of attacks they can execute, and therefore increasing the risk of data breaches."⁹

Risks covered by compliance monitoring program



The speed of evolving risks requires compliance teams to react and adapt faster than ever. Our life sciences respondents are intent on keeping up with and ideally getting ahead of such new threats. Ninety-one percent of respondents say that gaining new insights on potential risks is a priority. When it

comes to evolving regulation, for example, most emphasize the importance of keeping abreast of change. One compliance leader says: "If we see there are some regulatory changes coming up, we would want to make sure they are covered within the monitoring questionnaires."

⁹ Allianz Risk Barometer: Identifying the major business risks for 2024, Allianz Commercial/Allianz Global Corporate & Speciality SE, 2024.

Establishing more effective ways of working

To reflect this changing risk landscape, the life sciences compliance function is significantly evolving its delivery model and ways of working. Our findings show that all compliance teams are moving away from traditional structures and ways of operating to meet new risks and keep costs down. In doing so, they are boosting consistency and efficiency.

Most (82%) compliance leaders say they have "centralized" delivery models. One compliance leader cites the following drivers for this approach: "The biggest reason is consistency of approach where needed. The second point is being able to look at a consolidated view of the outcomes through the same lens." Centralization generally involves a global unit overseeing a centrally devised program supported by dedicated regional or local teams. One compliance leader says: "A part of our strategy is called a

"glocal" model, which means globally designed, locally implemented."

Such global-local partnership is becoming common practice as companies move away from a uniform top-down monitoring approach. Around three in four (73%) organizations now tailor their programs, checklists and protocols for each review, collaborating with local teams to reflect local regulations. The extent of local influence varies, depending on the level of delegated autonomy. Summarizing a local compliance team's contribution, one respondent says: "They have a very flexible tool in place. It is in the form of a Google Sheet where they get these standard questions that all should be asking but they have the opportunity to add their own market-tailored questions that are very specific to their market."

73%

of organizations now tailor their programs, checklists and protocols for each review, collaborating with local teams to reflect local regulations.



Moving to hybrid location monitoring

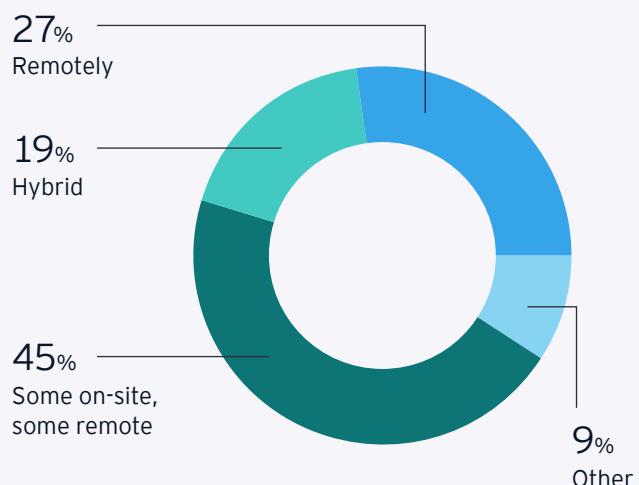
The locations from which compliance teams execute monitoring tasks, including the testing and reviewing of documentation, have also changed. Forty-five percent of compliance leaders now review both on-site and remotely, while another 27% do most of the work entirely remotely.

The COVID-19 pandemic expedited the move to such hybrid and remote monitoring when, almost overnight, social distancing required compliance teams to change how they executed operations and activities. Some local businesses subject to monitoring, particularly those still using manual processes, found they could not access essential documentation and needed to move quickly to a new way of working. This increased the risk of wrongdoing, making it all the more urgent for compliance teams to be able to work effectively to support their businesses. Such necessity accelerated the development of technology and processes to enable electronic access to data. This, in turn, became the driving force behind the move to a more hybrid post-pandemic model.

Although the COVID-19 pandemic was the main catalyst for remote working, organizational structure can also be a determinant. One respondent says: "The ones that are remote are the shared service centers because they are their own hub, logically separated from affiliates and they are fully electronic."

Having been driven by the exigencies of COVID-19, remote or hybrid working has delivered increased efficiencies. Reduced travel, for example – as well as helping companies meet sustainability targets – is assisting compliance teams in managing their budgets. Remote or hybrid working is also helping companies to give proportionate efforts to different parts of the business, in line with the level of risk.

Where monitoring execution takes place

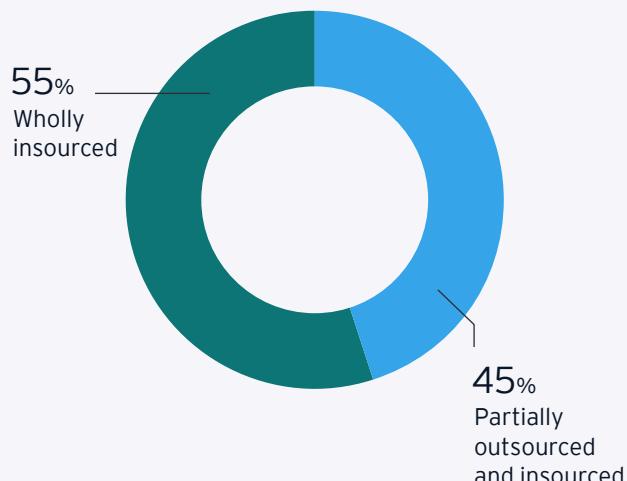


In an alternative centralized-hybrid delivery model, one life sciences company has established a nearshore compliance monitoring hub staffed by a multilingual team. The hub supports the company's global compliance monitoring program by executing upfront documentation pre-testing of transactions, which increases efficiency and reduces time pressures during fieldwork. The facility also helps generate insights by identifying key risk themes across markets and third parties. This resource complements the work of monitoring teams in other markets, including China and the US. The nearshore model has the additional benefit of enabling the organization to be more cost-effective in executing monitoring and do more within its budget.

Working with external providers

Companies are increasingly looking outside their own resources to deliver compliance. Forty-five percent of our surveyed companies outsource part of their monitoring programs, with 80% of respondents flagging cost efficiencies and lack of resource capability as the key factors. The need for specialist expertise – in areas such as risk management, language proficiency and technical ability – is a prompt for 40%. A number of companies use local external providers, with cost being a particular driver. Data analytics professionals also seek external specialist input; all use third-party providers, in such areas as delivering compliance analytics solutions, software applications and expansion, and data interpretation.

How the compliance monitoring program is managed

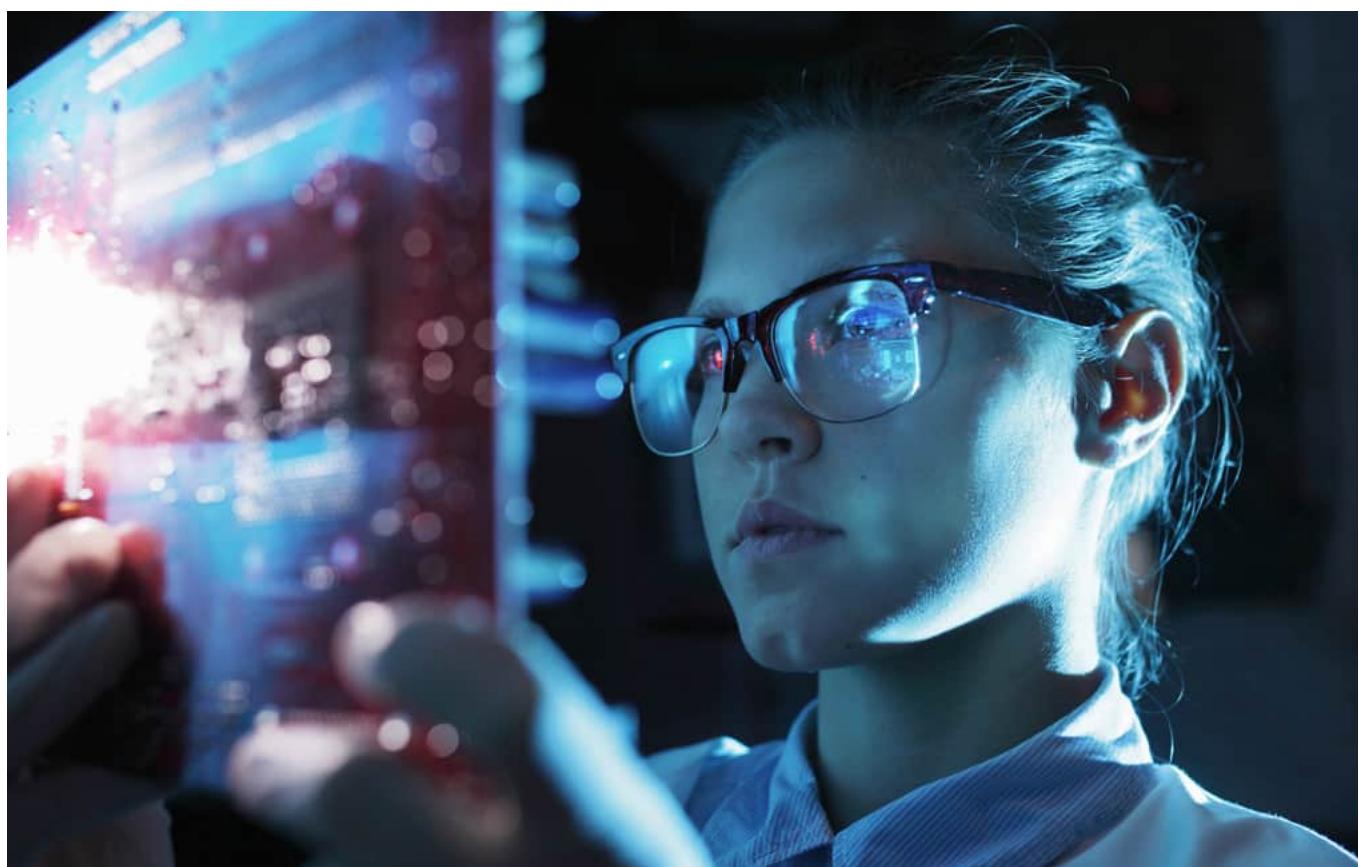


Standardization of global processes

Centralization often goes hand-in-hand with tech-enabled standardization of processes. Our findings suggest such global process alignment can enable greater consistency and efficiency overall. One compliance leader says: "I think the standardized approach for monitoring across countries is where we're strongest." Globally integrated systems are invaluable in enabling standardized processes, as another compliance leader's contrary experience suggests: "We have generally and traditionally been a very decentralized company with a lot of decentralized IT systems and processes, which makes it super hard to monitor from systems. A lot of the work that we do in the monitoring is still done manually."

Putting risk at the heart of process

The majority of organizations (91%) conduct compliance monitoring across all markets; in another evolution for the function, the way they do so has changed significantly. Whereas formerly corporate compliance functions often had a one-size-fits-all approach, they now increasingly shape their monitoring tactics to the severity of the risk. More than four out of five (82%) compliance leaders say they adapt their approach to reflect the assessment of market risk rather than, as previously, focusing on policy deviations within a broad, often universal, sample. One compliance head says: "Monitoring is based on the annual and quarterly risk assessment. We will identify the key risk area then do the monitoring."



Sample selection criteria table

1

Dependent on the risk factor

Sample size and selection is based on perceived risk.

2

Data analytics to identify trends

Risk scoring systems are used to select samples.

3

Frequency and complexity of activities

Sample selection is based on the number of transactions.

Information drawn from:

Internal sources

- ▶ Financial and transaction data
- ▶ Risk assessment and findings from previous audits
- ▶ Operational data

External sources

- ▶ Regulatory information
- ▶ Public information

Perceived risk is now a particular consideration in determining sample size and selection, as one compliance leader says: "The criteria for sample selection are based on country risk ratings. I think we have around ten subcategories of risk." The nature of an organization's activities also plays a part, suggests another: "We have a set number of samples that we aim for but it can very much depend on the complexity of the activity and how much documentation or, almost, different sub-activities sit within that sample." Risk professionals are now able to identify sample trends with data analytics. Another respondent explains: "We use a data analytics tool that will help flag the most risky transactions based on a number of different criteria." Although, as explored further below, data analytics now plays a significant role in sample selection – and the wider compliance sphere – individuals still play a crucial role in interpreting and understanding data and identifying items with the highest risk – a fact underlined by the continuing high demand for data analysts.¹⁰

As another example of "glocal" practice, a market's particular characteristics, in such areas as legislation, ways of working and product range, also play a part in wider risk assessment. As one respondent says: "There might be a product in a particular country or region that's got approval in that location ahead of others. We need to do more monitoring in that region with that particular product, to ensure that we're identifying any risks."

There is every sign that the compliance function will continue to change in response to evolving challenges and opportunities in coming years. Looking three to five, one compliance leader says: "It is going to be a more rapidly evolving space both as the automated pieces pick things up faster what is noncompliant is going to change faster, and how we monitor is going to change faster." Technology will be at the heart of that change.

¹⁰ "Data science skills in the UK workforce", UK Parliament website, post.parliament.uk/research-briefings/post-pn-0697.

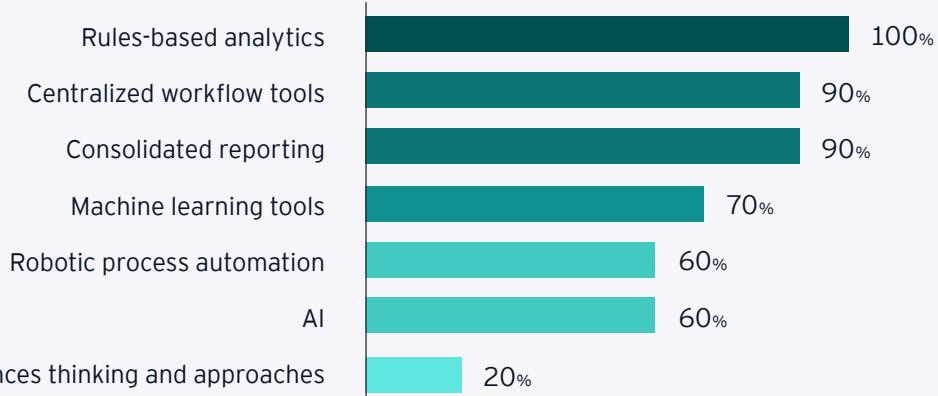
The promise of technology

As the compliance team's remit becomes broader and more complex, advanced technology and data analytics have the potential to not only help enhance efficiency in managing known risks but also play a crucial role in uncovering new and emerging risks. The EY viewpoint is highlighted in another report: "Data analytics, AI and automation greatly improve the ability to detect legal and reputational risks, describe them (typically in a quantitative way) and provide actionable insights."¹¹ It is a combination that has proven telling for businesses

from all sectors. Another EY survey found 70% of leaders from 300 global business were increasing spending on legal and compliance technology and 94% had adopted, or were actively adopting, automation to manage business risk.¹²

Our life sciences cohort has also invested in technology and data analytics. They all harness rules-based analytics to support monitoring, with 70% deploying machine learning tools and 60% using both robotic process automation and AI.

Tools and techniques used to support compliance monitoring activities



The most technologically advanced compliance teams find that tech is enabling them to be more responsive, faster. One says: "We hope for more real time so when things happen, you are able to spot them, on the spot, and that usually happens with the latest systems that we're implementing."

¹¹ "How to balance opportunity and risk in adopting disruptive technologies", EY website, ey.com/en_gl/insights/forensic-integrity-services/how-to-balance-opportunity-and-risk-in-adopting-disruptive-technologies.

¹² "The rapid rise of AI and the importance of data integrity and governance", *Economist Impact* website, impact.economist.com/projects/rapid-rise-of-ai.

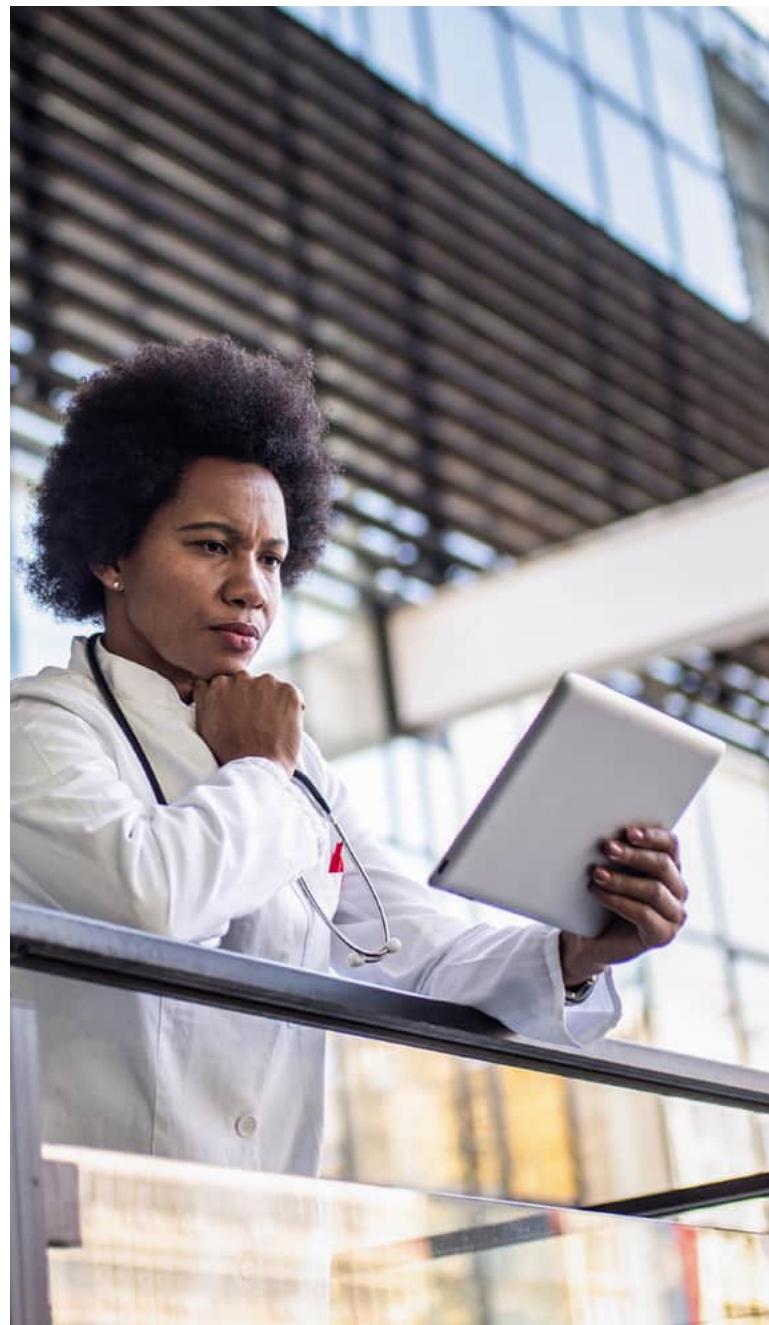
Some of the companies in the cohort are pushing the boundaries on using analytics for risk detection and mitigation, with examples including:

- ▶ A compliance chatbot for all employees that provides instant information on function processes and policies.
- ▶ Advanced behavioral techniques that identify teams more likely to initiate non-compliant events, with the aim of achieving early intervention.
- ▶ Leveraging innovative AI to build a network of third parties to identify conflict of interests and other risks.

In addition, compliance teams are also using technology for centralization, automation, digital workflow and case management. These tools are being applied across the compliance arc, particularly in risk identification and assessment and in tracking and reviewing emerging risks.

Key compliance benefits from analytics

- ▶ Identifying high-risk transactions
- ▶ Increased efficiency
- ▶ Real-time insights and trend analysis
- ▶ Detecting outliers and anomalies



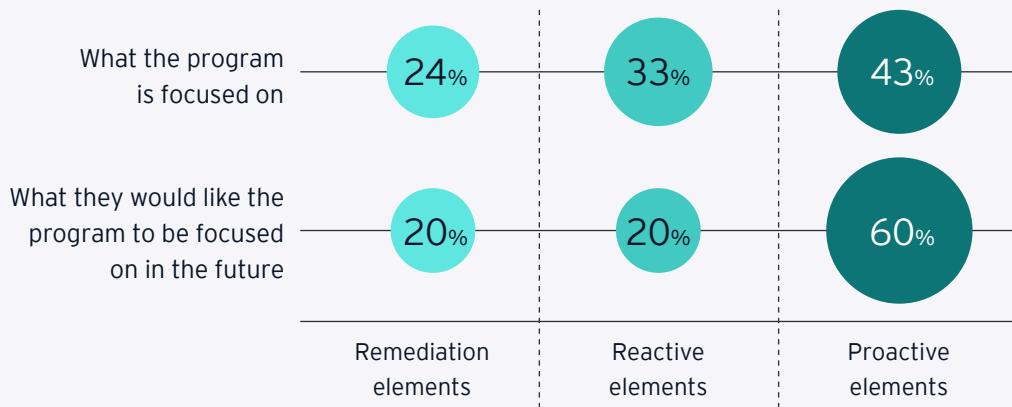
The challenges within the tech promise

Technology is not an off-the-peg cure-all, however. Life sciences compliance teams, in common with other functions and sectors, are having to overcome fundamental issues, such as complex data and system landscapes, inadequate and inconsistent datasets and legacy infrastructure. Despite some stand-out innovations, most life sciences compliance teams still seem at the beginning of the advanced tech journey. Although optimistic about the advantages technology will deliver, few are currently reaping the optimum benefits. It is telling that compliance heads identify “technology and innovation” and “data availability” as among the key challenges of the past two years. Applying data can also be problematic. One compliance chief says: “We have room to improve in data analytics and in really embedding that into our monitoring program. There's definitely room for growth in the analytics space.”

Limited integration of business systems is another stumbling block. One compliance leader says: “The technology that our business is using varies as well as the technology that compliance teams are using varies.” Such systems incompatibility frustrates the creation of a common pool of quality data – a requirement of effective data analytics.

Such challenges have a knock-on impact, leaving compliance teams following up on breaches rather than preventing them. Most compliance leaders would like 60% of their programs to be proactive – meaning they equip their businesses with the insights to prevent non-compliance – therefore reducing the focus on reactive elements to just 40%. But currently only 43% of activities are proactive, with 57% being remedial and reactive. One compliance leader says: “Retrospectively checking in later, you find what you have done, but you can't really do a lot about it anymore – what has happened has happened.”

Percentage of program focus



Some challenges may reflect certain life sciences compliance teams' relatively recent conversion to technology and data analytics. One function leader says: “I think the main challenge has been that we didn't

start using data soon enough to the full capacity of data analytics. We really only started using data analytics – which we refer to as “responsive” monitoring – to a large extent, this year.”

The quest for quality data

Many companies are struggling with one of the preliminary steps in the analytics maturity curve: the sourcing, collation and linking of good, accurate data. One says: "There is a lack of centralization of some of the data that's needed, especially on a global scale." Another acknowledges: "Our program is least mature in being able to aggregate analytics and to aggregate multi-factorial data."

Inadequate data does not just mean monitoring is less efficient or precise. It can also be hard to trust. And, as one data analytics professional indicates, trust is essential to achieving compliance team buy-in on advanced technology and analytics. "The first challenge will be making sure that our new way of doing things becomes the habitual way, so using the new versus the old way. We need to trust that data that is read by a machine and provides results to humans does not need to be rechecked. We need to be able to believe that the data is not hallucinated, that no mistakes or typos have crept in along the way."

“

There is a lack of centralization of some of the data that's needed, especially on a global scale.

Road to advanced analytics

Analytics professionals recognize the same challenges as compliance leaders. Despite 30% rating their compliance analytics as "advanced" and 60% as "intermediate," close examination of their survey responses suggests these verdicts are overstated. Even though 60% of data analytics professionals state they use AI, they appear to be evaluating it for simple use cases, like drafting policies and standards and for identifying red flags in expenses claims. Generally, significant investment in AI is still at the planning stage, with a few exceptions that appear to be pushing ahead. One respondent says: "We're looking at various predictive modeling archetypes to see how we could become more predictive. Another big area of investment will, of course, be machine learning and generative AI."

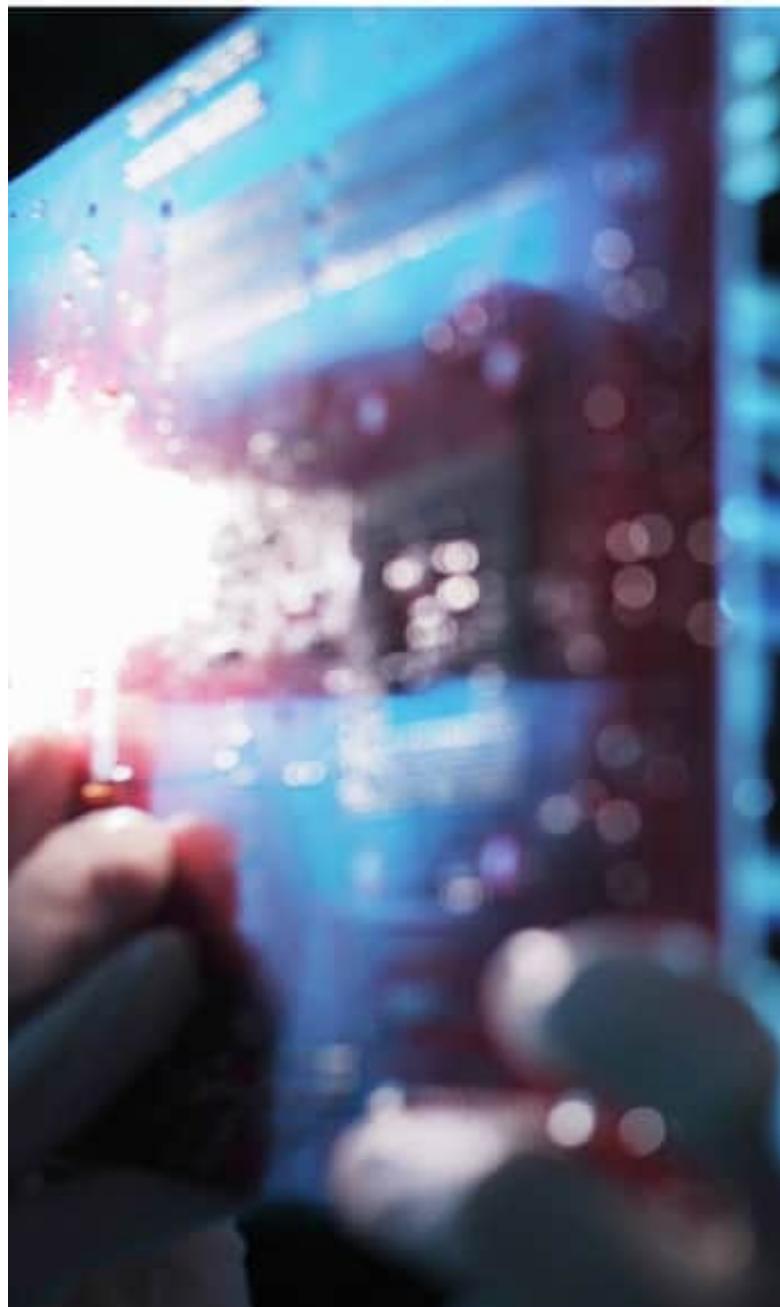
Data throws up external, as well as internal, challenges. Balancing the rewards of using AI and other advanced techniques with data privacy and ethical considerations is cited by compliance leaders as one of the top three business risks. One data analytics professional articulates the complexity of respecting data privacy: "You might need to directly identify some issues about an employee but you're of course very, very limited because you cannot use this type of data, you cannot outsource this type of data and even though you want to make a huge change you're limited because you need to respect people's personal data and the applications of responsible AI."



Investing in the future

Life sciences compliance leaders realize that tapping the full potential of advanced technology and data analytics will not be a quick fix. Although most function leaders consider their monitoring program "fairly mature," with more than one-quarter believing it is "very mature," most acknowledge there is room for improvement – and that improvement potential is normally seen in technology and data analytics. The majority acknowledge it will take between three and five years before they fully leverage analytics to identify patterns, trends and outliers; use AI to increase efficiency, automate and identify future risks; and apply technology to enable more real-time, regular monitoring.

Realizing these ambitions will take investment. The increasing respect for compliance's value as a business enabler may make such investment more likely – as may the growing C-suite understanding of the potential of analytics. One data analytics professional says: "Our leadership – our chief compliance officer and his peers in the C-suite – they're very much data driven and recognize the power of data and analytics to make decisions." Such top table support could reflect the fact that – beyond bolstering businesses' stand against risk – leading-edge compliance technology can strengthen their position with regulators. Government agencies are increasingly using AI and other data analytics tools to detect wrongdoing. Regulators expect companies to use similar tools. As one data analytics specialist says: "We know that the [U.S.] Department of Justice expects compliance to be utilizing data in the same way as the rest of the company. So it is an expectation that is being set by our CEO or our executive leadership team all the way down."



New skills for an evolved function



The change in the nature of the compliance function, and the tools and methods it uses, has inevitably had a knock-on effect on the skills it requires of its people. Effective remote reviewing, for example, requires people with the right skill set, language capability and understanding of local nuances. In another significant instance, the people spec for the compliance leader has changed. Now they must not only be an expert at interpreting risk, but in interpreting data too. The Institute of Risk Management says that "data analysis and modeling" is the second most important risk management skill, coming behind only "technical expertise." It says: "Risk professionals need to be adept at analyzing large volumes of data to identify patterns, trends and potential risks. Building skills in data analysis tools, statistical modeling, and data visualization can greatly enhance your ability to make informed decisions and provide valuable insights to stakeholders."¹³ Such analytical skills are likely to become even more essential. Envisaging the compliance function in three to five years, one function leader says: "It will be a lot more automated, a lot more digitized, with a lot more compliance by design. It will also be leveraging artificial intelligence."

“

Risk professionals need to be adept at analyzing large volumes of data to identify patterns, trends and potential risks.

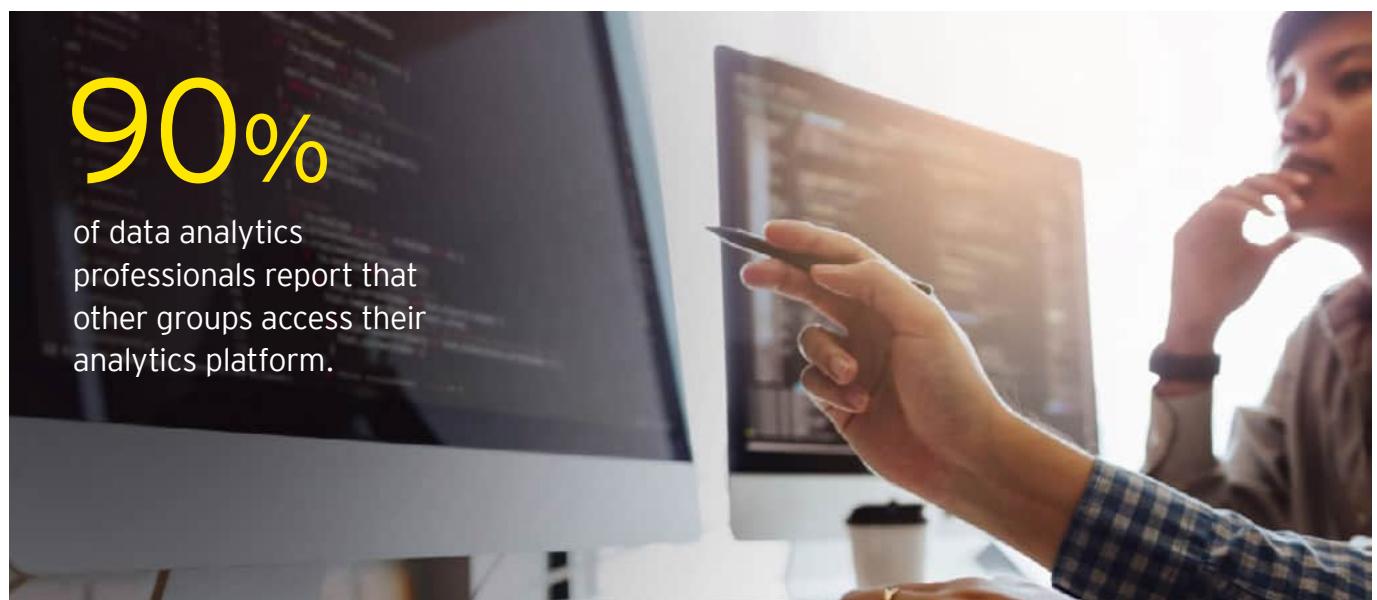
¹³ "Top 6 risk management skills and why you need them", *Institute of Risk Management* website, theirm.org/news/top-6-risk-management-skills-and-why-you-need-them.

Toward greater collaboration

Compliance team members must also now work more collaboratively, as different functions seek compliance-sourced data to unlock insights to help them manage risk and make informed decisions in their areas. Ninety percent of data analytics professionals report that other groups access their analytics platform. The extent of such sharing varies between businesses; ranging from those who give access to just audit and general managers and those who open it up company-wide. One respondent from a company with particularly wide access says: "Our assurance teams have access to this data: internal control teams, internal audit, compliance, business ethics and business integrity teams. They're united as a second line of defense across the company to make sure that all analysis performed by compliance is then embedded into the internal control process."

The value of sharing extends beyond data insights – and beyond assurance. The wider organization can now draw on insights from compliance monitoring to change the way they do business. In an example of particularly good practice, one business is incorporating learnings from compliance monitoring of third parties into supplier risk profiles, which influence whether and how a third party is used and for what purpose.

Compliance leaders believe the closer union between different teams will grow over the next three to five years. One predicts: "We will continue to have increased integration of all the assurance or control functions into really collaborated efforts or common teams. I think a lot of those lines will continue to blur to be able to provide more just-in-time support to the business and to really provide integrated risk solutions."



Addressing perennial challenges

In considering the key challenges of the past two years, compliance leaders highlight both new and old challenges. Mastering advanced technology and harvesting quality data are relative newcomers but they sit next to two perennial hurdles: organizational changes and inadequate or inefficient use of resources.



Key challenges of the past two years

1

Organizational changes

Teams have had to adapt to changes in the market model.

2

Resources and data availability

Teams have had difficulties with resource allocation and data consolidation.

3

Technology and innovation

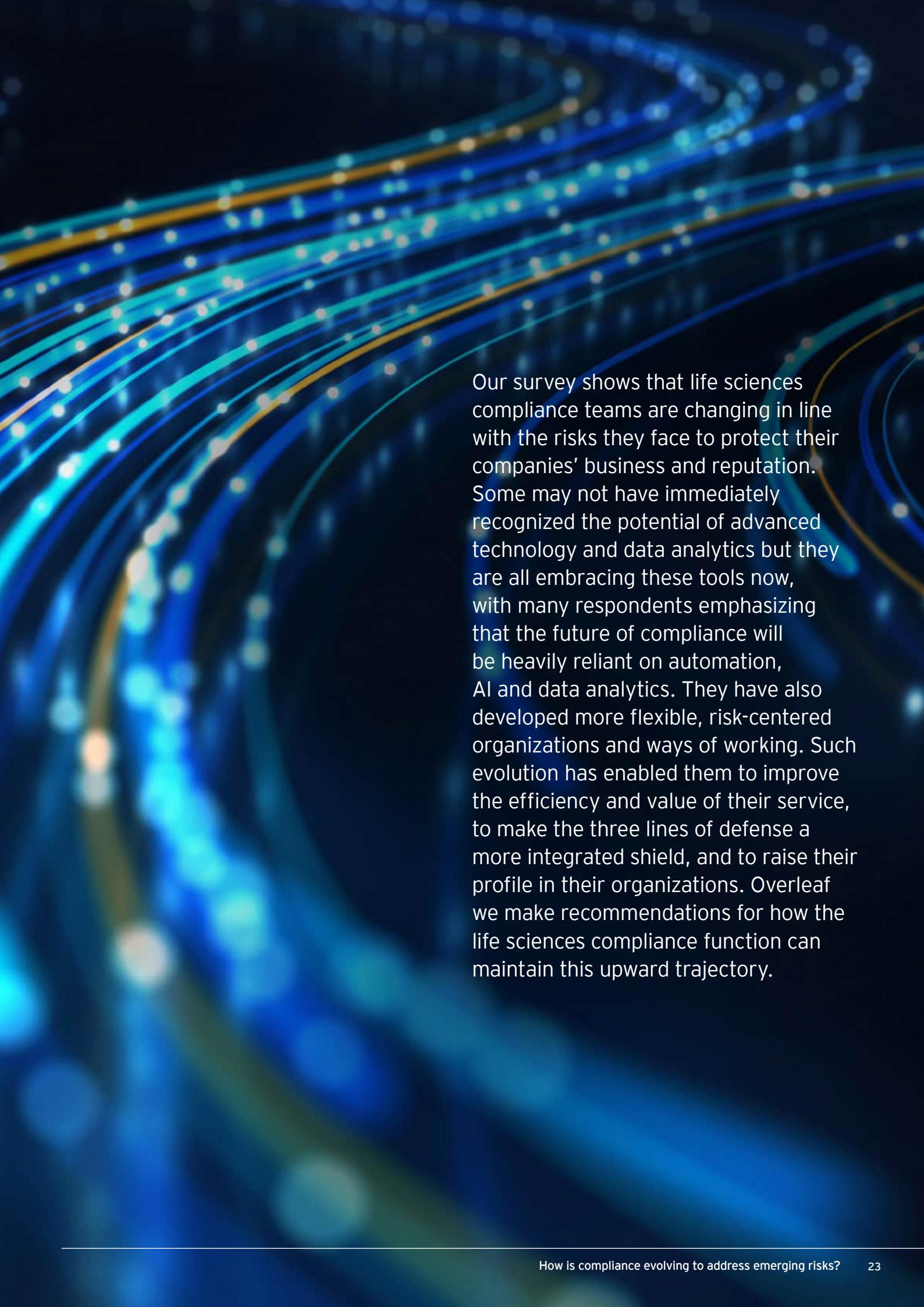
Teams have had to navigate the pace of change in technology.

When it comes to the challenge of organizational change, one compliance leader speaks of “an organizational transformation that has changed our go-to-market model and changed a lot of things, such as ways of collaboration and ways of working.” Such evolution is likely to continue as life sciences companies adapt their governance and change management strategies to manage new disruptive technologies, and go on looking to boost their competitive advantage through acquisition.

In regard to resources, reflecting a challenge of a more decentralized function, one compliance leader notes: “We keep emphasizing from global that there should be enough focus on the monitoring and some dedicated resources for monitoring but sometimes countries have challenges with that.” And a data analytics professional calls for “a more global analytics team with headcount actually sitting throughout the world.”

Conclusion

3 Maintaining compliance's upward trajectory



Our survey shows that life sciences compliance teams are changing in line with the risks they face to protect their companies' business and reputation. Some may not have immediately recognized the potential of advanced technology and data analytics but they are all embracing these tools now, with many respondents emphasizing that the future of compliance will be heavily reliant on automation, AI and data analytics. They have also developed more flexible, risk-centered organizations and ways of working. Such evolution has enabled them to improve the efficiency and value of their service, to make the three lines of defense a more integrated shield, and to raise their profile in their organizations. Overleaf we make recommendations for how the life sciences compliance function can maintain this upward trajectory.

- ▶ Balance centralization and local nuance. A centralized delivery model – particularly when complemented by integrated global systems and standardized processes – can deliver more effective use of resources, superior data collection and analysis, and more successful identification of risk. However, it needs to be balanced with an understanding for – and adaption of standard processes and tools to – local risk, enabled through close collaboration with teams on the ground.
- ▶ Approach your current and future talent needs for technology, and other disciplines, strategically in partnership with your HR team. Ask yourself what skills you will need to provide the service you aspire to deliver, where those skill holders will be based, and how much you will need to invest and when.
- ▶ Cross-pollinate ideas and experience. Our survey shows a pleasing trend toward greater collaboration between teams. Across the assurance realm, this could extend further to include investigations and procurement functions, for instance, and could incorporate common approaches, tools and training. Such integration would strengthen all three lines of assurance.
- ▶ Approach technology methodically. Identify your main challenges first and then consider how IT might help. You might not need a huge investment: you are likely to already have much of the tech you need within your organization. Start small with a pilot; set measurable targets in the areas of required improvements, such as in efficiency or transparency; and only expand when testing proves positive. Accept it will be a long journey, particularly if you do not yet have integrated systems. In all tech-related areas, work closely with your IT team.

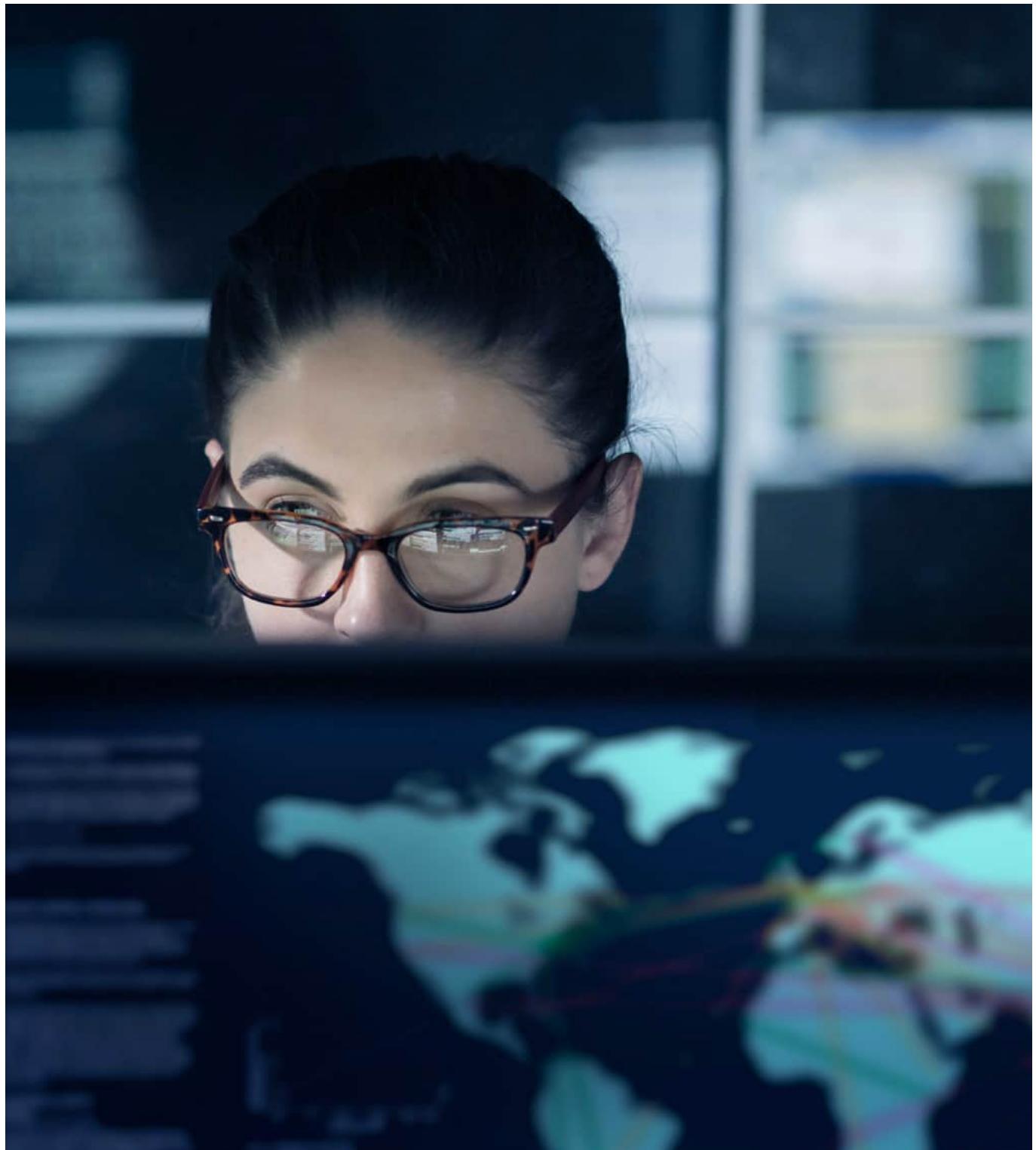
52%

of Financial Times-surveyed companies considered the loss of consumer trust as the biggest risk arising from irresponsible use of AI, above that of legal challenge.

- ▶ Ensure compliance technology does not create additional risks for the business. AI and automation may have the power to optimize operations and deliver valuable insights but they also amplify existing risks, such as data breaches, and can create new ones, like the unwitting violation of copyright laws. Make sure technology includes safeguards for proper, effective and objective working: for example, ensure AI has been trained on unbiased data. Consider strengthening internal controls to restrict data access and provide accountability.
- ▶ Ensure your company has a technology ethics policy. Technology is advancing faster than regulation and, spurred on by concern about generative AI, stakeholders are demanding that companies are proactive in committing to the responsible use of advanced tech. A recent *Financial Times* survey found that 52% of surveyed companies considered the loss of consumer trust as the biggest risk arising from irresponsible use of AI, above that of legal challenge.¹⁴ (In drafting a policy, companies may wish to refer to the World Health Organization's AI ethics and governance guidance for large multi-modal models, which covers scientific research and drug development.)¹⁵
- ▶ Support the development of a culture of integrity in your business. A commitment to doing the right thing is as important as the controls environment.

¹⁴ Murray, Sarah, "What does AI mean for a responsible business?" *Financial Times*, 27 March 2024.

¹⁵ "WHO releases AI ethics and governance guidance for large multi-modal models", *World Health Organization website*, who.int/news-room/18-01-2024-who-releases-ai-ethics-and-governance-guidance-for-large-multi-modal-models.



EY exists to build a better working world, helping to create long-term value for clients, people and society and build trust in the capital markets.

Enabled by data and technology, diverse EY teams in over 150 countries provide trust through assurance and help clients grow, transform and operate.

Working across assurance, consulting, law, strategy, tax and transactions, EY teams ask better questions to find new answers for the complex issues facing our world today.

EY refers to the global organization, and may refer to one or more, of the member firms of Ernst & Young Global Limited, each of which is a separate legal entity. Ernst & Young Global Limited, a UK company limited by guarantee, does not provide services to clients. Information about how EY collects and uses personal data and a description of the rights individuals have under data protection legislation are available via ey.com/privacy. EY member firms do not practice law where prohibited by local laws. For more information about our organization, please visit ey.com.

About EY Forensic & Integrity Services

Embedding integrity into an organization's strategic vision and day-to-day operations is critical when managing complex issues of fraud, regulatory compliance, investigations and business disputes. More than 4,000 EY forensic and technology professionals help leaders balance business objectives and risks, build data-centric ethics and compliance programs, and ultimately develop a culture of integrity. EY teams consider your distinct circumstances and needs to assemble the right multidisciplinary and culturally aligned professionals for you and your legal advisors. They strive to bring you the benefits of leading EY technology, deep subject-matter knowledge and broad global sector experience.

© 2024 EYGM Limited.
All Rights Reserved.

EYG no. 005799-24Gbl
BMC Agency GA 13521298
ED None

This material has been prepared for general informational purposes only and is not intended to be relied upon as accounting, tax, legal or other professional advice. Please refer to your advisors for specific advice.

ey.com/forensics