Getting the edge

Key insights on how to approach technology risks in life sciences which are worth taking

Background

Aiming for a technological edge in today's fast-paced marketplace may be one—or even the most—important factor to separate market participants from market leaders. But how can an organization get there without significantly increasing the (mostly unknown) risks that come with this new technological territory? Various promising emerging technologies (not yet fully adopted), such as blockchain, cloud-computing, artificial intelligence (AI), augmented reality (AR), virtual reality (VR), or low code/no code (LC/NC), are just some of the options organizations are taking a keen look towards. The key is to identify the ones that, in combination, leapfrog your organization's ability to accelerate your mid- to long-term strategies. However, there is no reward without facing risks. Because these technologies are not yet fully adopted, they pose inherent risks from a regulatory compliance perspective. In this article, we will share results from a recent technology risk survey, addressing emerging technology risks and regulatory compliance areas.

Understanding the data set

KPMG LLP (KPMG) conducted a survey in the summer of 2022 with a focus on healthcare and life science organizations. The data set provides insights from over 50 organizations. The makeup of the organizations involved is broken out by sector (as shown in Figure 1), as well as by organizational size (Figure 2), and by target audience (Figure 3).

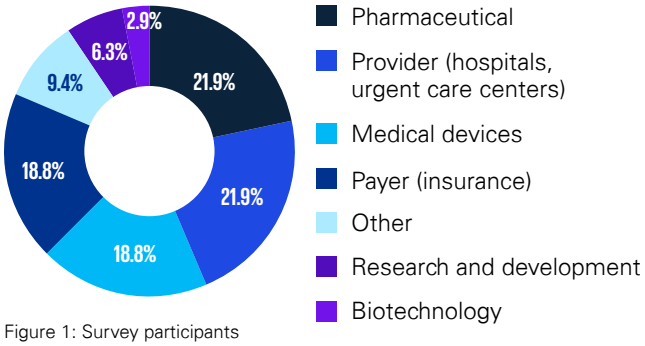

Figure 1: Survey participants

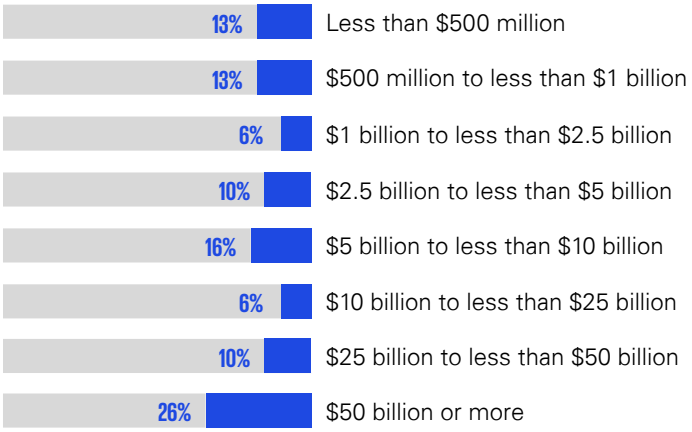

Figure 2: Participants' prior-year revenue overview

Our target audience focused on professionals who operate in the areas of compliance/risk management, internal audit, finance, and legal to get their perspectives and insights. With more than 58 percent, internal audit represents the largest population in this data set.

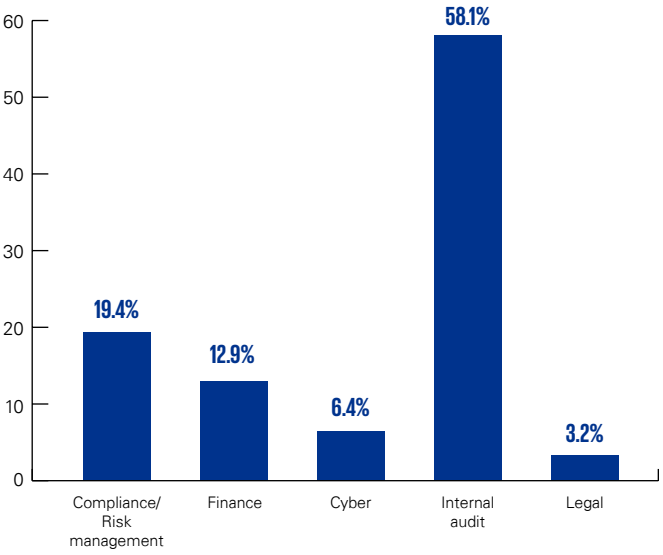

Figure 3: Distribution of participants per role

Same risks, differing approaches

Staff shortages, aging and obsolete technologies, cyber threats, and high volumes of regulatory compliance requirements—all are well-known reasons for an increasing complexity of an organization's process landscape. However, these are only a few examples that led our survey participants to choose "improving business process efficiency" (86 percent) as their top priority to tackle technology risks for the upcoming years.

First, high levels of investments lead to significant inorganic growth through acquisitions followed by complex and time-consuming transformation programs. To succeed, it is important to find the right balance between both new and existing technologies along with new processes. To achieve this, prioritize the design of a practical strategy to protect your data while also maintaining compliance and optimizing new processes.

Second, significant data is stored in outdated (legacy) technology environments with no clear strategy to streamline relevant processes. An analysis of required regulatory retention periods for the data in scope can be a first step when deciding on the timeline to shut down systems for good.

A third example known to generate process inefficiencies or even issues is—simply put—trying to work in areas that are not at the core of your business. For instance, internal audit performing assessments without the subject matter professionals for technical topics, e.g., cloud security or ransomware. Reflect on your organization's vision and if it may be beneficial to partner with subject matter specialists for specific activities or even functions (if only partially) not only for efficiency purposes but also to drive improved value and quality and to improve your overall risk management.

"Rapidly changing business conditions have driven the need to speed up digital transformation initiatives while addressing technology risk concerns.

Jason Glantz, KPMG LLP
Managing Director
Life Science Technology Risk Leader

Although these organizations' top priority may be similar, by analyzing each of the subcategories individually, their second priority paints a different picture. The majority of medical device organizations (83 percent) selected enhancement of the customer/patient experience, the majority of biotechnology organizations (80 percent) are looking to digitally transform the internal audit and/or compliance function. Pharmaceutical organizations also look at their customer experience but plan to develop new delivery methods (e.g., telehealth, remote patient monitoring) (87 percent), too, while research and development organizations make it one of their goals to reduce information technology (IT) maintenance and hardware costs (90 percent).

Technology challenges that life science organizations care about

Focusing on a different angle, when asked about the risks associated with the implementation of emerging technologies, our survey revealed "maintaining compliance with regulatory requirements" as the top response (26 percent). This is likely the result of the challenging endeavor to interpret regulatory requirements into technical language so the CIO, CISO, CRO, CAE, and the business, among others, can all speak the same language as it relates to their technology risk environment. For life sciences organizations, some of the biggest challenges lie in "good practice" guidelines and regulations, data protection laws (e.g., California Consumer Privacy Act, General Data Protection Regulation), and Sarbanes-Oxley. In our projects working with organizations, we combine teams with the right combination of legal/regulatory knowledge along with the right technical understanding to bridge the gap and translate these requirements into actionable items to maintain compliance.

Another prevalent response from our survey was "identifying risks and controls with newly implemented technologies" (19 percent). By taking a closer look, this refers not only to emerging technologies but also enterprise applications, such as Workday, Salesforce, SAP, ServiceNow, Oracle, Epic, and/or Cerner. The endless options to configure (leveraging native functionality) or customize such systems raise unique challenges in this highly regulated sector. The key point is to take the time to understand the impact of any configuration (preferred) or customization, which can change the functionality of the application and/or bring it out of support.

Two other observations stood out: First, the primary concern for research and development organizations is organizational adoption and how to train team members on new technologies (33 percent). This does not seem to be a technology challenge per se but more the challenge to enable the organization's workforce to use new technologies fully and in a controlled manner. Second, biotechnology organizations are most prominently concerned about data risk management (33 percent). In the context of increasing global privacy regulations and the explosion of data all around us, it is critical to establish the proper processes to govern the organization's data with a mindset of adhering to a multitude of legal requirements. There is no "one size fits all" model; the tools must fit the purpose—where a data leak might be the right choice for one organization, a blockchain model may be the right choice for another.

Solving technology risk conundrums

Our survey provides insights into life sciences organizations becoming more comfortable around the identification, evaluation, and mitigation of technology risks. However, the speed in which technology reinvents itself causes reasons for concern. To address this development, organizations need to understand whether their capabilities in technology risk management (TRM) require new talent and continuous investment in training activities rather than yet another tool.

Under the assumption that staff shortages are a factor, the survey revealed the top choices of the organizations' TRM program with the following results:

Figure 4: Top priority of the organizations' technology risk management program

There are a wide range of possibilities how to go about this. At KPMG, we start with the risk assessment. Organizations have historically leveraged a highly manual, qualitative, and judgmental risk assessment. As enterprise disruption continues, there is an increasing need for a more informed and more frequent assessment of risks. Organizations recognize the value of expanding inputs to be more data-driven and technology-enabled to streamline execution, but lack an understanding of which inputs to prioritize, the right data model, and development capabilities to do so efficiently or effectively. KPMG has developed a digital risk intelligence platform to help organizations perform their annual risk assessment as well as with their ongoing risk management. This platform leverages a combination of internal signals (e.g., survey/interview results, data from relevant applications) along with external signals (e.g., financial and operational data from the marketplace).

Life Science's subindustries do have diverging priorities for their second choice to enhance their TRM programs:

- Medical device organizations' place an emphasis on "improving monitoring of compliance and control activities (e.g., continuous monitoring)" (74 percent).
- Biotechnology organizations preferred two options, both at 80 percent: "better alignment of risk management approach to business strategy and objectives" as well as "improve coordination among risk functions."
- Research and development organizations' second priority is to "Improve collaboration and value to the business" (90 percent).
- Pharmaceutical companies clearly show a focus on HR and to "improve overall skills and talent" (90 percent).

In this regard, we suggest that interested readers look at another highly relevant thought leadership piece about the importance of workforce transformation during Covid-19 (source: KPMG International, June 2020).

While one focus talks about ensuring you have the right skills, at the right time, in the right place to constantly adapt to uncertain external trends, agile operating requirements, and rapidly changing customer demands, another focus is on how to lead people authentically and with compassion to reset your employee experience that thrives in a digital and remote workplace.

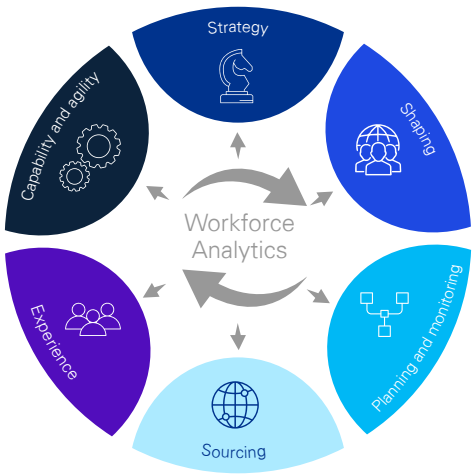

Figure 5: Key elements of workforce transformation

In our experience, addressing these elements will lead to efficiencies, effectiveness of control environment, and ultimately to reduced risk and a much more trusted value proposition.

The right technology for your approach

The KPMG survey goes one step further and asks life sciences organizations about their priorities when it comes to new technologies which shall help to achieve these goals. Medical device organizations (63 percent) as well as biotechnology (80 percent) and pharmaceutical organizations (80 percent) prioritize the ability and potential of cloud computing and are investing in these areas. At KPMG, we combine our modern technical skills and leading solutions with our deep business, industry- and domain-specific experience to help technology leaders succeed by accelerating their transformation efforts. That's speed to modern cloud. Find more information here.

Biotechnology organizations (more than 90 percent) are transforming their ERP technologies with new system implementations (e.g., Oracle, SAP, Salesforce, ServiceNow) while at the same time leveraging low code/no code (80 percent) to enable their citizen developers. Low-code application development changes the conversation from years to months, weeks, and days. Leading technology risk teams will update their controls strategy so that rapid software development and strong controls can go hand in hand. In the modern world of technology, and to move at a faster pace of change, there is a fine balance that needs to be struck, with close collaboration between the business, IT, and technology risk teams. For more details, please refer to our KPMG paper, "Citizen developer enablement," by clicking here.

Did you know?

In general, organizations implemented governance, risk, and compliance (GRC) technology to handle the risks associated with their complex IT environment five to ten years ago and are now looking to upgrade and gain more holistic benefits with these technologies, addressing cyber, risk and compliance, regulatory compliance, privacy, third-party risk, and other areas, with advanced analytical and automation opportunities. However, our survey shows that in life sciences, more than one third (37.5 percent) claim their GRC technology is challenging to leverage and/or not well utilized.

From the data set, Research & Development organizations are the only ones that show a higher focus on Blockchain use cases to further their goals (70%). As Blockchain is a system in which a record of transactions is maintained across multiple computers (nodes) that are linked in a peer-to-peer network, it removes the need for intermediaries. A blockchain-based tracking solution in Life Sciences helps R&D as well as pharmaceutical companies monitor where their products are located based on scans of unique identifiers at each stop in the supply chain. All parties involved have a single source of truth and receive real-time updates depending on permissions. That also involves a multitude of new risks. KPMG provides an experienced lens to understanding, developing, and maintaining the security and compliance of distributed ledger technologies.

Overall, there has only been a moderate involvement into the application of artificial intelligence (including machine and deep learning). Based on individual inquiries, this technology has a very strong potential but as of today only very limited use cases.

Conclusion

The life sciences sector is facing interesting times with the potential to continue to leverage emerging technologies while maintaining controls and compliance. Leading organizations will be proactive and get a jump on understanding risks from emerging technologies and new trends before they become mainstream or dominant. At KPMG, we understand your challenges and can provide an objective perspective on various technology risks your organization may be facing. This may include performance of a current-state maturity of your technology risk environment to support a new technology stack, replacing obsolete software, how to transform your risk assessment process, or other techniques to better leverage emerging technologies.

Our professionals can leverage an outcome-based capability model to help ensure your technology risk program aligns with highest value for your business and achieves the desired level of compliance, effectiveness, efficiency, and scalability. KPMG can also provide the integration of technology risk specialists and technologists to help bring a proactive view of risk and solutions that fit your needs. Our technology risk services include:

- TRM capability assessment
- Target operating model and roadmap for transformation
- IT policy, standards, and framework adoption
- IT risk training and awareness
- Technology, process, or program risk assessments
- Compliance risk assessments
- Data/technology/platform risk assessment
- IT risk and control due diligence in mergers and acquisitions and pre-IPO
- IT internal audit risk assessment.

For further information on some of the technologies mentioned in this article, please refer to this link.

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