Life Sciences businesses continue to grapple with TPRM challenges

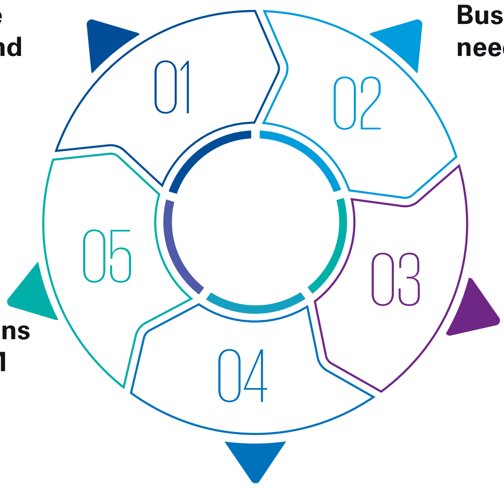
Lack of technology, skills and funding cited as key issues in KPMG survey

Life Sciences

The journey to effective third-party risk management (TPRM) is continuing for today's life sciences organizations amid an array of significant challenges.

As the economic recovery picks up speed in today's hyper-competitive environment — and in the face of supply-chain disruptions, cyber threats and inflationary pressures — TPRM has become more important than ever. New research by KPMG International shows, however, that life sciences businesses are struggling with significant TPRM issues that include insufficient skills and budgets, underperforming technology, growing threats to business continuity and evolving regulatory requirements.

KPMG's *Third-Party Risk Management Outlook 2022* included participation by 1,263 senior TPRM executives working for organizations operating in six major global industries. And as our findings indicate, despite progress by some life sciences firms pursuing TPRM maturity, the outlook for many shows no shortage of challenges — with most actually reporting that 'luck' rather than effective TPRM helped them avoid a major third-party incident during the current pandemic.



Third-party incidents are disrupting businesses and damaging reputations

Businesses underestimate the need for strategic programs

Technology is failing to deliver on its promise

The challenge of limited resources is here to stay

Life sciences organizations lack fit-for-purpose TPRM programs

01 Third-party incidents are disrupting businesses and damaging reputations

KPMG's *Third-Party Risk Management Outlook 2022* report notes, among its five key themes, that third-party incidents are disrupting businesses and damaging reputations.

Mitigating risk is proving to be a major challenge for life sciences businesses, with 76 percent experiencing 'supply-chain disruption, monetary loss or reputational damage' as a result of third-party incidents within the last 3 years. Most, 73 percent, say TPRM program inefficiencies have exposed them to brand and reputational risk. More than half (57 percent) say they have been overbilled by a third party in the last 12 months and 69 percent call value leakage around third-party billing a 'growing concern.'

In our experience, many of today's TPRM programs remain disjointed, cumbersome and lacking an enterprise-wide, risk-based approach. In many cases, technology remains a key issue in terms of how it is being chosen and implemented — typically lacking strategic alignment across the business regarding TPRM requirements, functionality and execution.

Our advice is to focus on creating TPRM programs that are truly fit for purpose, as defined by each organization's unique risks, challenges and requirements. The good news is that we are seeing more life sciences businesses evolving in this direction, typically stepping back to assess whether their TPRM programs are delivering as intended — and where they need to go to enhance risk management. You cannot mitigate every risk — so focus on a fit-for-purpose approach that addresses those risks that are most critical to your unique business environment and third-party network.

For example, we see some smaller companies, such as startup biopharmas, strategically pursuing a 'crawl-walk-run' approach to TPRM. Recognizing they will not be 'best in class' given their size and limited resources and budgets, they are undertaking 'as a first step' key activities such as prioritizing risk assessments and due diligence among their highest-risk third parties.

02 Businesses underestimate the need for strategic programs

KPMG's report notes that businesses are underestimating the need for sound TPRM programs and appropriate budgets, citing too much reliance on tactical initiatives over a strategic, enterprise-wide approach to TPRM.

Two-thirds believe TPRM is undervalued given its increasingly critical role and 51 percent say they lack sufficient in-house TPRM capabilities to manage risk. More than two-thirds of firms (68 percent) say funding is mainly spent on 'business-as-usual' resource costs rather than strategic improvements, and 69 percent say managing cyber risk absorbs the bulk of spending.

More than three-quarters (77 percent) believe TPRM should be playing a 'much more active role' on business continuity, while 79 percent say they 'urgently need to make TPRM more consistent across the enterprise.'

It's not surprising, among our findings, that life sciences businesses are dedicating significant budgets to cyber-risk management in today's environment of costly cyber attacks, geopolitical volatility and the financial health of third parties. But this too often comes at the expense of implementing integrated TPRM programs that are consistent across the enterprise. Doing so starts with getting the *process* right — there is no 'silver bullet' or one-size-fits-all solution that the quick implementation of technology will deliver. Yet this is a mistake we often see — businesses implementing a patchwork of technology initiatives while failing to adopt a strategic approach to risk management that is absolutely essential.

> **79%**
> Say they 'urgently need to make TPRM more consistent across the enterprise.'

03 Technology is failing to deliver on its promise

Despite high hopes for technology, our research shows that existing tools are often proving to be unsatisfactory or burdensome among sector organizations. Fewer than half (43 percent) of TPRM tasks are currently automated and just 56 percent of firms anticipate having some level of automation included in their TPRM programs within 3 years.

Most firms (58 percent) are frustrated by the significant lack of 'visibility' that technology is providing around third-party risk and business continuity. Most (61 percent) also report 'too much grey area' in their business when deciding which team is responsible for which aspect of business continuity.

Key challenges to TPRM transformation cited by firms include data-breach concerns (34 percent) and integration challenges (31 percent), while 28 percent also cite a lack of skills/capabilities, inconsistent approaches across the business and poor ROI.

61%

Report 'too much grey area' in their business when deciding which team is responsible for which aspect of business continuity

We typically see TPRM teams relying on workflow solutions to support processes, while across risk functions connected to TPRM, various platforms and third-party service providers support the execution of due-diligence activities. Leadership teams typically expect TPRM to be covered by individual functions or business units, while overlooking the significant synergies that a coordinated approach can deliver. Overcoming the technology issues hindering TPRM programs inevitably demands that firms take a truly risk-based and integrated approach that is enterprise-wide.

While our findings illustrate the challenges that sector businesses are struggling with on the technology-implementation front, the good news is that as more organizations reassess their TPRM programs, they are recognizing the critical importance of taking a strategic approach to TPRM — ideally focusing on modern programs that are integrated with partner functions throughout the business, such as procurement, legal and finance.

04 The challenge of limited resources is here to stay

In today's complex and hypercompetitive business environment and the accelerating pace of change, the challenge of managing limited resources will likely continue for life sciences businesses. Digital tools can help shoulder the burden to some degree but the playing field continues to widen as TPRM's remit expands across all risks, domains and third-party types.

Life sciences businesses cite tech innovation (45 percent), cyber risk (40 percent), financial instability (36 percent) and business continuity (34 percent) as TPRM risks that have grown most rapidly in recent years. As our findings show, however, just 30 percent of today's sector business are assessing third parties prior to contract, while 29 percent are monitoring post contract. The number of businesses assessing every third party for ESG-related risks also remains low — 22 percent for environmental risks and 28 percent for social and governance, with those numbers expected to increase in 3 years' time to about 30 percent. Progress on third-party assessment, including ESG-related risks, remains slow.

Amid the growth of risks across third-party networks, prioritizing the use of limited business resources has become critical for life sciences organizations. Taking a risk-based approach that allocates resources to highest-risk third-party arrangements is the way forward.

05 Life sciences organizations lack fit-for-purpose TPRM programs

As noted, our research reveals that sector businesses are struggling with TPRM programs that too often fail to deliver. More than half (52 percent) agreed that 'luck' rather than effective TPRM helped them avoid a major third-party incident during the current pandemic. And most (70 percent) agree that they still have a 'long way to go' for their TPRM function to act as a true strategic partner to the business. About four in five (79 percent) believe the pandemic crisis has made it clear that an 'overhaul' of their operating model is overdue.

As our findings show, the pandemic has served as a wake-up call on the need to reassess and enhance TPRM capabilities and operating models. Most organizations struggling to reach TPRM maturity often lack even the core elements of an effective operating model that is integrated across the business. Many need to shift their focus, replacing tactical initiatives and short-term, quick-fix solutions with strategic, enterprise-wide TPRM engagement that delivers appropriate visibility and transparency among all third parties.

It's not just about getting 'quick wins' or simply remaining reactive to emerging challenges. Today it's about implementing an appropriate governance and resource model, and fit-for-purpose policies and procedures, to help ensure that the TPRM program is executed successfully. Many of our clients are assessing their resource model and also re-evaluating third-party on-boarding protocols amid today's fast-changing environment.

Navigating the journey toward TPRM maturity

TPRM should be high on agendas this year as life sciences businesses grapple with the challenges cited in our findings and the realities of the post-pandemic era. Sector businesses at the early or medium stage of maturity should have programs that position them to manage every third party appropriately. Success is expected to require the following steps:

— **Pre-contract to due diligence:** Complete appropriate due diligence prior to executing contracts. Key risks such as business continuity, reputation, cyber security or compliance can be prioritized over other risks.

— **A risk-based approach:** Don't assess each third-party engagement with the same level of depth. Amid limited time and resources, focus first on third parties that impact critical services, expanding efforts as the TPRM program matures.

— **Ongoing monitoring:** For third parties supporting critical services, life sciences organizations should establish ongoing monitoring to help ensure that the third party is consistently meeting expectations over the lifetime of the contract.

— **Program governance:** Oversee, monitor and manage all relationships, with roles and responsibilities clearly defined in order to enhance decision making and rapidly resolve issues.

Life science businesses at a more advanced stage of maturity should ideally focus on the following steps to optimize TPRM programs:

— **Automation:** Organizations are looking to automate workflows, using technology to accelerate processes and decision-making while enhancing cost efficiencies. To complete tasks for various components, businesses can also leverage industry utilities to streamline the due-diligence process.

— **Taking a risk-based approach:** To further streamline the risk tiering of third-party services, tighten the criteria used to define what is critical or high risk. This may include:

  — Using light-touch programs for homogenous groups of third-party services with a standard risk profile;

  — Proceeding straight to a purchase order when there is nominal risk in a service;

  — Processing the remaining standard contracts through the third-party program and evaluating the need for on-site due diligence.

— **Off-boarding and disengagement:** Organizations should understand how they can exit a relationship when performance is unsatisfactory, while striving to ensure that services remain uninterrupted. Mapping specific services to products and processes within the organization is essential to success.

— **Service-delivery model:** We see an ongoing trend for businesses to establish an enterprise-wide center of excellence that may or may not be centralized. The center of excellence is an efficient way for organizations with limited resources to cover their third-party network. A unified framework supports consistency across the program, enhanced data quality, and accountability between the central team and relationship owner.

— **Management of fourth parties and affiliates:** In mature programs, fourth parties — as well as intercompany and intracompany transactions — are no longer out of scope. Businesses therefore should have appropriate controls that include contract documentation and consistent alignment with existing TPRM program requirements.

KPMG can support TPRM leaders in achieving their goals

Today's TPRM leaders should have a structured and phased approach in order to gain appropriate levels of attention and investment from their boards and management. KPMG professionals are providing TPRM teams and life sciences organizations with support for the following crucial activities: programs that position them to manage every third party appropriately. Success will likely require the following steps:

— **Assessing requirements and program scope:** A crucial first step is identifying how regulation is evolving across jurisdictions. Many global regulators are scrutinizing third-party risk management from a broader outsourcing perspective, with a sharper view on privacy, cyber security and ESG, for example. Ensuring compliance with regulations and being prepared to respond to regulator queries to avoid financial or reputational damages is a key TPRM program requirement.

  An effective TPRM program also relies on the integration of diverse components among processes, people, delivery models, governance, data and technology. Understanding program performance and capabilities across these areas can reveal the organization's current level of maturity and where to act among existing strengths and weaknesses — ultimately illustrating whether the operating model is fit for purpose and sustainable.

- **Transforming the TPRM program:** KPMG has developed a model end-to-end TPRM program based on our collective cross-industry and global experience. Our unique Powered TPRM program represents an 80-percent solution of what good looks like, while allowing for configuration according to specific client requirements. While our model is technology agnostic, it is designed with leading governance, risk and compliance (GRC) platforms that support rapid implementation while enhancing the program it supports. There is no one-size-fits-all approach to TPRM — calibrating a full suite of components for a mature organization is vital to every program's success.

  Uplifting an enterprise-wide TPRM program is a major initiative that requires a clear roadmap, sufficient resources and full leadership commitment. Technology automation and capitalizing on the digitization trend will likely continue in the coming years. In response, KPMG has developed relationships with key technology and industry utility providers to help drive efficiencies around process and due-diligence automation, and the continuous monitoring of controls. We are driving greater integration across TPRM, procurement, contract-lifecycle management and other risk functions to take advantage of advances in these areas.

- **Running the program and planning for the unexpected:** A fully operational TPRM program requires more resources to execute the pre- and post-contract assessment and monitoring activities. TPRM capabilities encompass a cross-organizational operating model and practitioners need a wide set of skills to manage the full suite of risks. This can make it harder to secure all capabilities internally.

As our survey highlights, life sciences organizations are being challenged by limited resources and skills and thus seeking more efficient ways to manage TPRM activities. Some are relying on diverse technology enablers and alternate delivery models to address their capability gaps and enhance efficiency.

Given our strengths in risk and compliance, along with our global footprint, we are helping clients execute the ongoing risk-assessment components of their TPRM programs, including cyber reviews, control assessments, sanctions and anti-bribery and corruption reviews, among others. This allows for momentum to be established around the program while helping to manage costs.

Key takeaways

In conclusion, our advice to businesses pursuing the journey to TPRM maturity is that there is no time to waste in today's fast-moving environment and the accelerating pace of change. As new risks and challenges emerge, businesses cannot afford to sit still or rely on quick fixes. TPRM maturity is a journey that requires businesses to invest the time, funding and resources needed to reach their destination with effective, future-focused programs that are truly flexible, scalable and sustainable.

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