

ICON plc

Best in Class Third Party Risk Management – Large Enterprise



CASESTUDY

Governance, Risk Management & Compliance Insight

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ICON plc

Best in Class Third Party Risk Management – Large Enterprise

The Modern Organization is a Web of Relationships

“No man is an island, entire of itself; every man is a piece of the continent, a part of the main.”¹

Replace the word ‘man’ with ‘organization’ and the seventeenth-century English poet John Donne is describing the modern company. In other words, “No organization is an island unto itself; every organization is a piece of the broader whole.”

The structures and realities of business today have changed. Gone are the years of simplicity in operations. Exponential growth and change in risks, regulations, globalization, distributed operations, competitive velocity, technology, and business data impede third-party relationships and the business’s ability to manage them. Traditional brick-and-mortar business is outdated: physical buildings and conventional employees no longer define the organization. The modern organization is an interconnected web of relationships, interactions, and transactions that span traditional business boundaries. Layers of relationships go beyond traditional employees to include suppliers, vendors, outsourcers, service providers, contractors, subcontractors, consultants, temporary workers, agents, brokers, dealers, intermediaries, partners, and more. Complexity grows as these interconnected relationships, processes, transactions, and systems nest themselves in intricacies, such as deep supply chains and subcontracting relationships. Roaming the hallways of an organization means crossing paths with contractors, consultants, temporary workers, and more. Business today relies and thrives on third-party relationships; this is the extended enterprise.

In this context, organizations struggle to govern their third-party relationships and too often manage risk and compliance within those relationships in silos that fail to see the big picture of risk exposure and the impact on the relationship’s objectives. Risk and compliance challenges do not stop at organizational boundaries. An organization can face reputational and economic disaster by establishing or maintaining the wrong business relationships or allowing good business relationships to sour because of weak risk governance. Third-party problems are the organization’s problems and directly impact the brand and reputation, increasing exposure to risk and compliance matters. When questions of delivery, business practice, ethics, privacy, safety, quality, human rights, resiliency, corruption, security, and the environment arise, the organization is held accountable, and it must ensure that third-party partners behave appropriately.

¹ A famous line from English Poet John Donne’s *Devotions Upon Emergent Conditions* (1624) found in the section *Meditation XVII*.

The business's ability to achieve corporate objectives directly depends on the governance of third-party relationships and whether the organization has established the right connections and can reliably achieve objectives in the relationship. The organization's ability to manage uncertainty, risk, and resiliency in its relationships requires that its objectives, values, and risks be managed together. Corporate integrity is measured by its relationships as well. The saying, "Show me who your friends are, and I will tell you who you are" translates to business: show me who your third-party relationships are, and I will tell you who you are as an organization.

What further complicates this is the exponential effect of third-party risk on the organization. Business operates in a world of chaos. Applying chaos theory to business is like the 'butterfly effect,' in which the simple flutter of a butterfly's wings creates tiny changes in the atmosphere that ultimately impact the development and path of a hurricane. A small event cascades, develops, and influences what ends up becoming a significant event.

Dissociated data, systems, processes, and a myopic risk vision leaves the organization with fragments of the truth that fail to see the big picture of third-party performance, risk, and compliance across the enterprise and how it supports its strategy and objectives. The organization needs to have holistic visibility and situational awareness of third-party relationships across the enterprise. The complexity of business, intricacy, and interconnectedness of third-party risk data requires that the organization implement a third-party risk management strategy.

The bottom line: The modern business depends on, and is defined by, the governance, risk management, and compliance of third-party relationships to ensure the organization can reliably achieve objectives, manage uncertainty, and act with integrity in each of its third-party relationships. A haphazard department and document-centric approach for third-party risk management compounds the problem and does not solve it. Organizations need to address third-party GRC with an integrated strategy, process, and architecture to manage third-party relationships with real-time information and risk intelligence.

ICON plc

Best in Class in Third Party GRC Management – Large Enterprise

ICON plc is a world-leading healthcare intelligence and clinical research organization. From molecule to medicine, ICON advances clinical research providing outsourced services to pharmaceutical, biotechnology, medical device and government and public health organizations. ICON develops new innovations, drive emerging therapies forward and improve patient lives. ICON is uniquely positioned as a midstream supplier of critical services to manufacturers, distributors, and service providers.

As a contract research organization for life sciences firms, ICON must protect their highly sensitive client data while outsourcing to over 5000 suppliers. This high-risk supplier population provides niche services such as drug transportation, Electronic Data Capture, and Telehealth, which require regulated systems to keep sensitive information in check.

What's more, ICON has been up against the common challenges of GDPR, cyber-attacks and tighter data privacy regulations. ICON faced particular exposure to third party, not only within their own network of third-party relations, but also as a supplier of goods and services themselves. Managing this web of relationships was both a matter of critical importance to their own operations and part of their value proposition to their clients. In response to an upcoming acquisition, ICON decided to evaluate its supplier risk management strategy to put itself in a better and more sustainable position for the future.

To get a handle on risk for an upcoming audit and acquisition, ICON evaluated their third-party management strategies and systems to identify critical weaknesses and increase its effectiveness. It was obvious that the system needed to mature in several ways, as manual processes and a vast amount of critical operations relied on a relationship management strategy that struggled under its own weight.

The company recognized that their manual supplier management would not suffice as they prepared for the acquisition. At the time, ICON relied on manual Excel-based and pen-and-paper methods. These methods were error prone, slow, and forced the team to take a reactive stance, focusing on the most urgent risk rather than building a proactive defense against their entire risk landscape. They lacked agility to proactively identify and address problems and visibility into their own risk profile. They required tools and systems that would reduce manual efforts and provide a platform that would enable proactive decision-making and clear communication regarding their risk profile.

One of ICON's biggest objectives was to decrease their average lead time for critical products and services. In other words, it was taking too long for procurement to get business-critical services and products onboarded, which extended the time it took to enable the services for use in clinical trials. Procurement also needed to get a handle on the value that services and products brought to the organization. The company wanted to be able to reject or offboard suppliers that didn't add value to the organization, yet they lacked the insight to do so.

Lastly, ICON faced a significant assessment burden and inconsistent risk calculation model. They used a root and branch assessment of the first 300 suppliers they onboarded. With this limited system, vendor questionnaires were stacked in a way that required multiple surveys to be sent out in succession. The legal team would then have to decide if contract changes were needed. The process was time and resource-draining across multiple departments. For an organization dealing with lots of PII, sensitive data and highly regulated systems within the FDA, efficient supplier management wasn't nice-to-have – it was a necessity.

To address this challenge, ICON developed an approach that involved revisiting their strategy, processes, and technology.

Third Party GRC Management Strategy

In preparation for the move to a Third-Party Risk Platform, ICON revisited the organization's purpose, strategic focus, and foundations. The company began by addressing their challenges with a solution provider that shared their core principles

– innovation, trust, and teamwork. Most importantly, ICON set the expectation early on that driving excellence from its supplier base was a collaborative responsibility. Procurement needed buy-in from other departments to get a holistic picture of risk outside of their purview. That meant that everyone in the organization would be responsible for monitoring risk and performance.

ICON aimed to align the goals of their supplier management function with the business' mission: to improve the lives of patients by accelerating the development of customers' drugs and devices through innovative solutions. To achieve this, they needed to accelerate their process for completing clinical trials and getting services to business units. It was clear that reducing friction in onboarding and performing ongoing due diligence would play a critical role in improving the lead time and quality of ICON's products and services.

Strategically, ICON focuses on four main tenets: patient access and engagement; career development and employer of choice; enduring customer partnerships; healthcare intelligence and applied innovation. These all had to be prioritized through the building of procurement's supplier management program. However, such prioritization would require the team to be in a position that would allow them to be proactive about these goals when managing suppliers.

ICON had a strong foundation from which to accomplish these goals. Above all else, they were committed to operational excellence, quality and delivery. Procurement, legal, and supplier management played the biggest role in maintaining this foundation across its suppliers.

ICON had a strong organizational vision that gave supplier management a baseline from which to revamp their program. They standardized accountability for performance and risk beyond their function. Lastly, they aligned their objectives to support the company's broader mission.

Third Party GRC Management Process

Before adopting a solution, ICON relied on a manual process to manage their supplier base. They sought to improve their assessment, risk calculation and continuous monitoring processes as these were the areas in which they were weakest.

To begin, ICON adopted a universal supplier request process. They leveraged a supplier management portal as a central point-of-contact for different departments to submit supplier requests. From there, they were able to store and reference end-to-end information on a given supplier. This process helped them to organize critical supplier information that could be accessed by a variety of interested parties. It also served as a centralized point for conducting due diligence on existing suppliers, providing a clearer picture for risk management. This reduced friction and provided clarity for the due diligence process.

ICON implemented a retroactive assessment process that allowed them to re-evaluate risk across their existing suppliers. They replaced their root and branch assessment

process with conditional logic to calculate risk more efficiently. This helped the team get a clear picture of the risk they were already exposed to and to better define the risk environment they occupied. They rewrote their questionnaires to begin with the suppliers' function within the organization – training, marketing, patient advocacy groups, IT infrastructure support, patient recruitment services or electronic data capture – then determine if the supplier is regulated and cloud based or has federal US government involvement. Based on their function and regulation level, the supplier receives questions on general information and sustainability, finance information, services and regulatory information, QA, information technology and/or data privacy. The assessment responses may also need IT validation or federal IT government support. These changes helped to unify information and to draw a map of where and how a supplier affected ICON's operations and risk profile.

Additionally, ICON added a periodic/continuous assessment process to stay on top of risk throughout the relationship. One of the organization's primary concerns is ESG, which needs to be monitored consistently due to its rapidly evolving nature. The addition of periodic assessments enabled ICON to pinpoint and recalculate risk at specific suppliers as needed. This change in strategy allowed the risk management team to gain the initiative and react with agility in response to emerging risks within their supply chain. This change contributed to ICON's goals to reduce friction and onboarding lead times while also increasing quality and reducing risk.

Third Party GRC Management Technology

ICON chose ProcessUnity Vendor Risk Management as the technology solution to manage their program. With a growing supplier base and an acquisition looming in the background, they needed to get organized quickly and deploy automation tools to expand their capabilities.

ICON started out by creating a supplier management portal as the foundation of their program. This served as the centralized location for due diligence efforts. This portal served as the de facto access point for supplier information, giving interested parties a concrete place to both begin and end their efforts. A centralized portal proved so valuable that the program was rapidly expanded to adopt several related portals, including contract management (both vendor and sponsor), site contracting and a regulatory intelligence database. These instances were easily configured to integrate with internal clinical trial system, GANTT charts and an EcoVadis connector. ProcessUnity and ICON prioritized a rapid build and deployment for the implementation and were able to generate a tremendous amount of value for the organization in a short timeframe.

The internal clinical trial system file integration within Site Contracting allowed ICON to move away from excel and manual processes. Previously, the internal clinical trial system had to wait on project managers, emails, and other data gathering efforts before they could begin negotiations. Now, the system runs the file every night automatically and identifies when negotiations can begin, thereby leading to swifter negotiation and speeding up of the overall process.

GANTT charts are utilized within the regulatory intelligence database and allow teams to select individual countries to observe specific data, monitor predictive insights, anticipate

next steps and identify country-specific clinical trial regulations. This allows sponsors to pick the most optimal distribution locations to get sites to initiation quicker and with less friction.

ProcessUnity helped ICON to scale rapidly. They were able to grow the number of unique users on the platform from 11.5% in 2018 to 27.8% in 2022. The team also finds that automated e-mail notifications help keep cycle times on track. In just a year, ICON reduced their average onboarding time by 50%.

The solution enabled ICON to adopt a full-fledged assessment engine for both retroactive and ongoing assessments. Bulk distribution with in-flight scoping sped up the assessment process, while response flagging drew attention to critical risk information. The added EcoVadis sustainability ratings connector provides validation into ESG areas of concern during the assessment process.

The Vendor Contract Management Portal features a general intake form that covers legal, procurement support and purchase requisition. Since implementation, procurement support tickets have fallen from 200 a month to 75. Additionally, ICON could identify repeat trends and common issues from the insights provided in the tickets. From this ICON developed training materials to aid staff in avoiding these issues in the future. The portal also features a SOW repository for every clinical study ICON has historically contracted. This information helps improve historical data analysis and reporting. Within the portal, teams can generate reports in a couple of minutes versus the old practice which took multiple weeks of disparate data gathering.

With the Sponsor Contract Management Portal, ICON is used as a repository for agreements and amendments. In addition, it is used to generate consulting agreements.

Benefits ProcessUnity Delivered to ICON plc

This delivered a completely holistic view of the supplier ecosystem and risk landscape to ICON plc. Specifically, it enabled:

- Rapid time-to-value: ICON was achieving results within weeks of initial directives
- Enterprise-wide accountability for risk mitigation initiatives
- Seamless integration, updates and change management
- Non-technical user enablement on the platform – driving accessibility and adoption
- Faster, more organized audits
- Direct communication with senior management

The process is best in class because it drives value across the organization and saves cost while providing the data and insights the organization requires. This has made ICON more efficient, effective, and agile.

Efficient

ICON's approach improved the organization's operational speed by unifying previously disparate functions. Operational efficiency times have improved throughout the extended organization since the implementation of a universal supplier management portal. This centralized information allows ICON to make better purchasing and contract decisions without having to chase down information or go through laborious data collection and verification efforts. Meanwhile, procurement and legal have the data they need to quickly review contracts, which has greatly expedited cycle times.

Spending less time on reporting allows ICON to focus on analyzing risk. They can invest less effort and generate higher quality reports while quickly communicating with the relevant stakeholders.

ICON has transformed their audit practice from a bureaucratic nightmare to an organized process. Their approach improved data accessibility, consistency and accuracy, enabling auditors to seamlessly review relevant areas.

Cross-functionally, ICON has reduced the amount of duplicative work being completed. The team has been able to free up their resources to focus on higher-priority mitigation tasks and maintain an agile risk management posture.

On top of these operational efficiencies, ICON spends much less time on managing the platform itself. The procurement support team has seen a reduction in issue tickets from 200 a month with their legacy platform to 75 a month with ProcessUnity.

Effective

ICON's approach has driven their overall effectiveness by providing clarity into the areas that needed attention. Since achieving holistic risk visibility, the organization can focus on risk by priority.

The business benefits of their supplier management program have extended beyond procurement. ICON has driven effectiveness throughout the organization by improving operational efficiency across several cross-functional groups, which increased the speed of business.

Faster operational speed also means that ICON can win business more quickly. The organization has improved their business effectiveness by improving their clinical study time, expanded their supply chain capabilities, and driven a higher quality extended enterprise. This all has contributed to ICON's value proposition to its clients, which in turn has culminated in increased profitability for the organization.

In addition, this process allowed ICON procurement teams to integrate faster than any other department come time for acquisition. The Supplier Management Portal was already embedded, and the entire team had switched to this new system from their previous manual process. As a result, suppliers were integrated into the system quicker and allowed the roll out of retrospective assessments for these to be moved forward by 6 months.

Agile

Since implementing ProcessUnity, ICON can dynamically assess risk across various domains and departments, enabling a proactive approach to supplier management. With historical and trend data at their fingertips, ICON is positioned to anticipate supplier issues before they can affect the business. Additionally, ProcessUnity gives ICON near-full autonomy in their change management. They have the confidence to meet the business' evolving needs with ease, be it another acquisition or a new regulation.

Further, ICON's approach has bolstered the organization's resilience by improving their incident response and proactive risk management. With synchronicity between departments, the organization can swiftly address issues from a unified front.

ICON Achieved Best in Class Third Party GRC

GRC is an integrated capability to reliably achieve objectives [GOVERNANCE], address uncertainty [RISK MANAGEMENT], and act with integrity [COMPLIANCE].² Successful GRC strategies deliver the ability to effectively mitigate risk, meet requirements, satisfy auditors, achieve human and financial efficiency, and meet the demands of a changing business environment. GRC solutions should achieve stronger processes that utilize accurate and reliable information. This enables a better performing, less costly, and more flexible business environment.

GRC 20/20 has evaluated and verified the implementation of ProcessUnity at ICON and confirms that this implementation has achieved a remarkable case study in how to address third party GRC/risk management with clear benefits achieved.

This approach is "best in class", and in that context GRC 20/20 recognizes ICON and ProcessUnity with a 2023 Best in Class GRC Award in the Category of Third Party GRC Management – Large Enterprise (Over 10,000 employees).

GRC 20/20's Final Perspective

ICON achieved all of this with full integration in just 12 months. Previously, ICON's IT system maintained a separate program from procurement. With ProcessUnity, the entire organization can operate on a single platform and eliminate the need to find and reconcile information from different systems.

² This is the official definition of GRC found in the GRC Capability Model and other work by OCEG at www.OCEG.org.

Specific value points include:

- Report generation was reduced from two weeks to minutes: With the click of a button, ICON can easily generate reports on key program data for senior leadership and auditors. Resources are freed up for higher-priority risk activities.
- The consultant agreement export time was reduced from ninety minutes to four minutes: This reduction contributes to ICON's faster operating speed, as it freed up resources to work on other opportunities.
- 'Art of the Possible:' High platform configurability means that the team can easily configure the platform to meet any use case without extensive service engagements.
- Significant reduction in cycle times for the site contracts.
- Study timelines are shortening.
- Holistic visibility of data led to improved win rate.

ICON's future roadmap will focus on supplier performance and governance. The implementation team envisions a single production ecosystem across the organization and its supplier base. Looking ahead, they'll further configure their ecosystem to map performance data to risk across every department.

The future roadmap will also include the leveraging of ESG data via the Ecovadis connector to ensure that the suppliers meet the standards ICON are setting for themselves in this area. This means that inclusion and diversity components will be expanded on. The ESG data and the inclusion and diversity components will become part of ICON's supplier scorecard in the future.

ICON will also add an automated rejection process for underperforming or otherwise unfit suppliers. This will be a gamechanger across the organization as it will reduce the amount of wasted resources going towards relationships that do not add value, and further raise the bar for quality throughout the organization's supply chain.

About GRC 20/20 Research, LLC

GRC 20/20 Research, LLC (GRC 20/20) provides clarity of insight into governance, risk management, and compliance (GRC) solutions and strategies through objective market research, benchmarking, training, and analysis. We provide objective insight into GRC market dynamics; technology trends; competitive landscape; market sizing; expenditure priorities; and mergers and acquisitions. GRC 20/20 advises the entire ecosystem of GRC solution buyers, professional service firms, and solution providers. Our research clarity is delivered through analysts with real-world expertise, independence, creativity, and objectivity that understand GRC challenges and how to solve them practically and not just theoretically. Our clients include Fortune 1000 companies, major professional service firms, and the breadth of GRC solution providers.

Research Methodology

GRC 20/20 research reports are written by experienced analysts with experience selecting and implementing GRC solutions. GRC 20/20 evaluates all GRC solution providers using consistent and objective criteria, regardless of whether or not they are a GRC 20/20 client. The findings and analysis in GRC 20/20 research reports reflect analyst experience, opinions, research into market trends, participants, expenditure patterns, and best practices. Research facts and representations are verified with client references to validate accuracy. GRC solution providers are given the opportunity to correct factual errors, but cannot influence GRC 20/20 opinion.

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