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Accelerating Digital Transformation and Driving Business Success: the Crucial Role of Process Mining in the Life Sciences Industry

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Introduction

The life sciences industry is evolving rapidly in response to macroeconomic shifts, regulatory changes, cost pressures, large data volumes, and increasing competition. This transformation is presenting challenges for the industry, particularly in the areas of raw material management, drug efficacy, adherence to safety norms, and patient experience. To address these challenges and take advantage of emerging opportunities in this dynamic space, life sciences enterprises need to invest in digital transformation initiatives and scale them to strengthen their value chains and achieve their business objectives.

However, organizations in the life sciences industry often struggle to realize the desired results from their digital investments. All too often, they implement digital solutions such as AI, analytics, and automation without thoroughly understanding their business processes and, thus, fail to meet their digital transformation goals or achieve any tangible Return on Investment (RoI). Additionally, this lack of process understanding can exacerbate inefficiencies across the life sciences value chain.

Therefore, it is important for life science enterprises to understand and optimize their business processes before they implement any technology solution and scale their digital transformation programs. They should leverage process mining technology to discover, document, and improve their processes to successfully implement digital transformation initiatives and maximize their RoI.

Today, process mining has widespread applications across many industries, including life sciences, and is being leveraged across different stages of the life sciences value chain, such as clinical trials, drug manufacturing, pharmacovigilance, inventory management, and quality control. Notably, life sciences organizations that have implemented process mining have accelerated their digital transformation journeys and achieved superior business outcomes.

In this viewpoint, we examine:

- The life sciences industry's current state, including key trends and challenges
- Introduction to process mining
- Process mining adoption in the life sciences industry
- Key barriers and best practices to accelerating process mining adoption

The report will benefit business leads charged with improving operations, digital transformation and automation leaders, and process excellence teams.

The current state of the life sciences industry

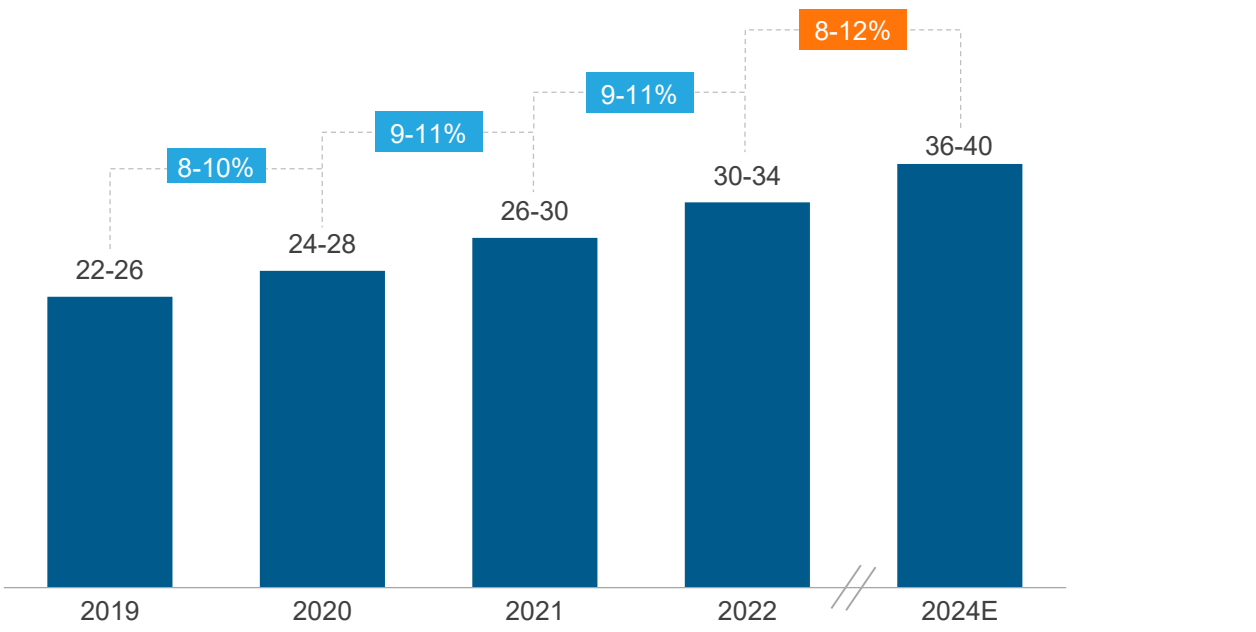
Key market trends impacting the global life sciences industry

Emerging market dynamics and evolving patient needs are shaping today's global life sciences industry. Increasing regulatory requirements, R&D investments with an emphasis on evidence-based innovation, and the need for operational excellence are driving digital adoption. The life sciences operations outsourcing market is projected to grow at a CAGR of 8-12% over the next two years and reach about US$40 billion by 2024. Exhibit 1 illustrates the overall spending on life sciences operations outsourcing.

EXHIBIT 1

Overall spend on life sciences operations outsourcing
US$ billion, 2019-24E

Source: Everest Group (2023)



The life sciences industry has witnessed consistent growth over the past few years, and we expect this momentum to continue going forward.

Some of the key trends, challenges, and opportunities in the industry are:

- **Macroeconomic challenges – inflation and rising interest rates**
  Life sciences companies operate in a dynamic industry, which necessitates continual monitoring and adaptation to macroeconomic changes across regions. Due to inflation and high interest rates, life sciences companies are dealing with increased costs of raw material, manufacturing, and distribution, which impacts overall profitability and financial performance. Interest rate fluctuations also impede life sciences companies' ability to invest in R&D, potentially slowing innovation and drug development.

- **Growing data volumes**
  The life sciences industry is faced with the challenge of managing, analyzing, and interpreting ever-growing data volumes. The availability of abundant data from sources such as clinical trials, patient records, genomics, imaging, and real-world evidence offers an opportunity to extract valuable insights, enabling informed decision-making and enhanced outcomes. However, ensuring data privacy and security is paramount, given the increasing data volumes and sensitivity. Adherence to strict data protection regulations and robust security measures, such as encryption and access controls, are vital to maintain patient privacy and prevent data breaches.
- **A complex regulatory landscape**
  The regulatory landscape poses both challenges and opportunities for life sciences companies. In the life sciences industry, the drug approval process is complex and involves navigating stringent regulations. Regulatory bodies such as the Food and Drug Administration (FDA) and European Medicines Agency (EMA) oversee the approval process, which includes preclinical and clinical trials, safety, and efficacy assessments. Companies need to establish robust systems to monitor and report safety concerns, including adverse events and drug interactions. Additionally, life sciences companies must prioritize IP protection to safeguard their innovative discoveries, research, and proprietary technologies, ensuring a competitive edge in the market and enabling the potential for commercialization and exclusivity.
- **Rising consumerism and the need for personalized care**
  The life sciences industry is responding to the growing consumerism and demand for personalized care by adopting patient-centric approaches, harnessing digital technologies such as data analytics, AI, cloud computing, and automation and expanding remote healthcare options. Life sciences companies are developing personalized solutions to meet individual needs and integrating digital health solutions into their products and services. The industry is shifting to patient-centric clinical trials, involving patient input in trial design, recruitment, and outcomes measurement. This shift toward consumer-focused, personalized care is reshaping the life sciences industry and driving innovation in the delivery of healthcare services.

Evolving objectives of life sciences organizations

Life sciences organizations' priorities and objectives are shifting significantly in response to industry trends. These objectives include:

- Accelerating R&D investments: Enterprises are increasing their investments in R&D efforts and allocating more resources to speed up research and innovation and bring new therapies, treatments, and solutions to the market faster
- Achieving digital transformation at scale: Recognizing the capabilities of new technologies, life sciences organizations are actively pursuing digital transformation projects to enhance research, development, manufacturing, distribution, and patient care processes
- Driving partnerships and collaborations: Organizations are forming partnerships and collaborating with numerous stakeholders, such as research organizations, healthcare providers, and technology companies, to promote innovation, exchange ideas, and solve complex problems
- Future-proofing the supply chain: Life sciences organizations are proactively adopting strategies to future-proof their supply chains, including diversifying sourcing options, investing in advanced logistics and distribution technologies, and implementing robust risk management practices

- Transforming the patient experience: Life sciences organizations are focusing on enhancing the overall patient experience by personalizing treatments, improving accessibility, and fostering proactive engagement and communication
- Streamlining the business model to meet regulatory mandates: Organizations are adopting robust quality control measures, implementing efficient reporting systems, and ensuring adherence to ethical and legal standards to maintain compliance with regulatory requirements

These evolving priorities enable life sciences organizations to remain competitive, drive growth, and address changing patient and industry needs.

Drivers for digital transformation in the life sciences industry

The COVID-19 pandemic has not only posed challenges to the life sciences industry but also accelerated the adoption of digital technologies. The need for digital transformation has become crucial for organizations to enhance operational efficiency, improve patient outcomes, and adapt to the rapidly evolving landscape. Embracing digitalization will enable life sciences companies to navigate challenges effectively and leverage new opportunities that arise in this dynamic ecosystem.

Digital transformation in the life sciences industry involves the digitalization of processes across the value chain. The pandemic has underscored the importance of digital technologies in streamlining various processes – from drug discovery and clinical trials to manufacturing and supply chain management, organizations are leveraging digital solutions to improve efficiency, reduce costs, and accelerate timelines. These digital solutions have not only helped maintain the momentum of ongoing research and clinical trials but also opened new avenues for patient-centric care, enabling individuals to access healthcare services from the comfort of their homes.

Key challenges for scalable transformation in life sciences organizations

The life sciences industry encompasses a wide range of processes, from R&D to manufacturing, regulatory compliance, and quality control management. These processes often involve large volumes of data, legacy systems, and complex supply chains. As a result, enterprises struggle to gain a comprehensive view of their end-to-end processes and understand the interdependencies between different functions and departments. The lack of process visibility and transparency hampers the ability to identify inefficiencies, bottlenecks, and opportunities for improvement. Organizations operating in the life sciences industry face the following key challenges in their journeys:

- Data integration: Integrating and harmonizing data from clinical trials, research studies, adverse events, and IoT devices is a major challenge in understanding processes. Moreover, data is continuously generated from different enterprise systems and custom platforms, which makes it difficult to gain a holistic view of processes
- Complex supply chains: The life sciences industry has complex supply chains that involve multiple processes and stakeholders. Achieving process visibility and transparency across these interconnected processes is difficult due to information silos, diverse systems, and data incompatibilities
- Collaboration with process owners: Lack of collaboration with process owners is a major barrier to comprehending processes. A siloed approach also leads to improper monitoring and analysis of process metrics

- Legacy systems: Enterprises in the life sciences industry continue to use old legacy systems that may not be designed for efficient data-sharing and may create obstacles in accessing and analyzing data. This fragmented data landscape hampers the ability to derive valuable insights
- Organizational barriers: Resistance from employees to embrace new initiatives and technologies is a key challenge, which can be attributed to a lack of awareness. This, in turn, makes it difficult to get executive buy-in for such initiatives

Maintaining a balance between process visibility and transparency while adhering to regulatory requirements can be challenging, especially when managing confidential information and proprietary data. To overcome these challenges and unlock ways to improve operations, life sciences organizations should leverage process mining.

Introduction to process mining

Definition of process mining

Process mining refers to a technology that can:

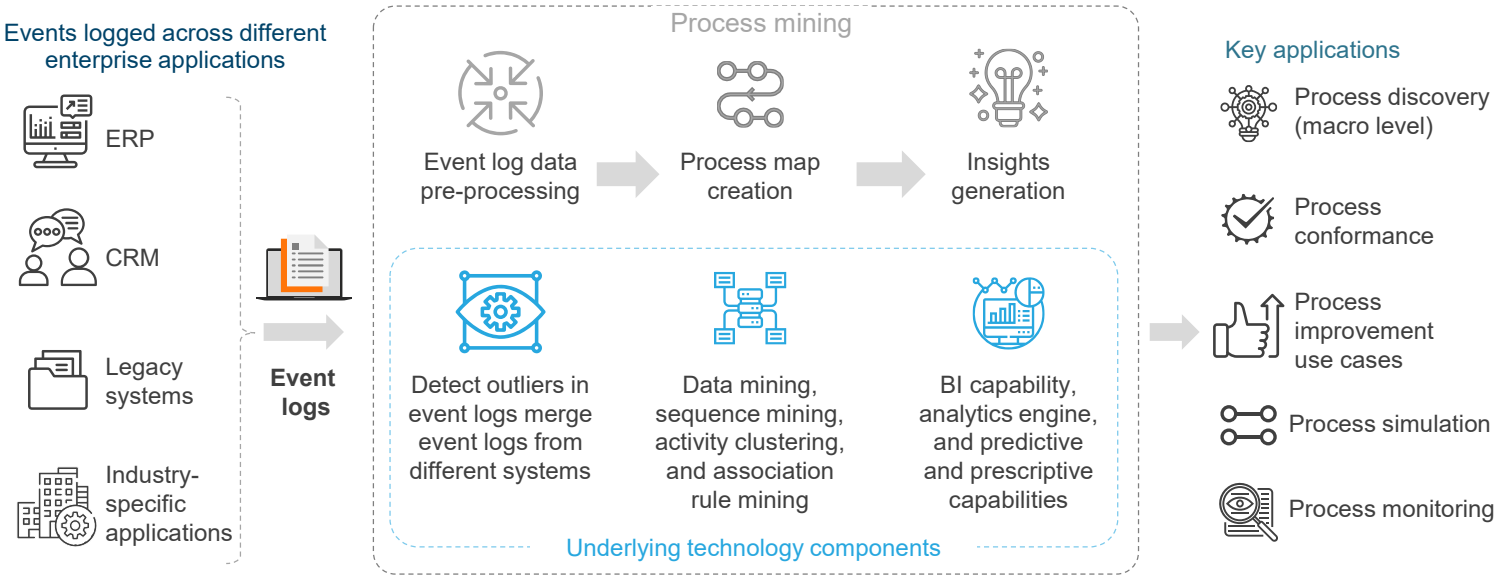
- Collect event log data from different information systems, such as ERP and CRM, containing date, time stamp, unique ID, and activity, which are further analyzed to discover processes
- Generate process maps that capture the different process variants with the sequence of tasks/steps involved
- Extract relevant business insights, such as process discovery, root-cause analysis, process conformance checks, and process benchmarking

Exhibit 2 presents an overview of process mining.

EXHIBIT 2

The process mining architecture

Source: Everest Group (2023)



Applications of process mining

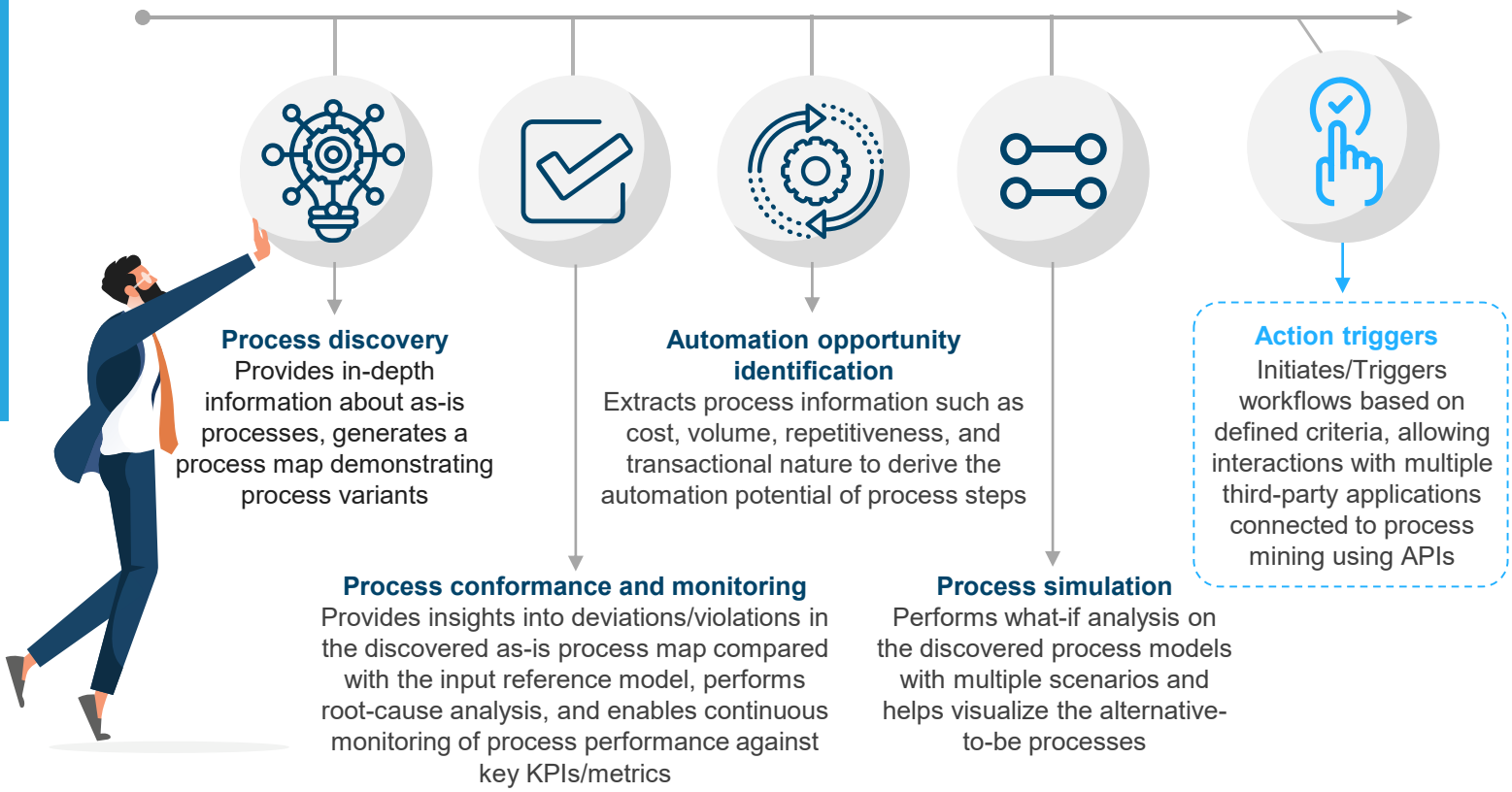
Process mining solutions have a wide range of applications in generating fact-based insights from processes and assisting with the transformation of these insights into actions. Exhibit 3 offers a detailed overview of the various process mining applications.

> Process mining applications, such as process discovery, conformance, and monitoring, provided greater visibility into processes, helped identify the root cause of problems, and delivered actionable insights.
>
> – Executive Director – GBS Digital Services, Global pharmaceutical company

EXHIBIT 3

Applications of process mining

Source: Everest Group (2023)



All these applications enable enterprises to gain a comprehensive understanding of current business processes and detect and eliminate inefficiencies using a data-led and fact-based approach.

How are life sciences enterprises leveraging process mining?

Current process mining adoption maturity

The process mining market has seen a strong 50-55% YoY growth, reaching US$900-920 million in 2022. This trend is expected to continue in the years ahead, driven by the need to increase operational efficiencies, reduce costs, and improve process governance. Manufacturing, BFSI, CPG & retail, and healthcare & life sciences are the leading adopters of process mining solutions. Healthcare and life sciences grew 40% YoY in 2022, with a significant proportion of this growth attributed to life sciences organizations.

The adoption of process mining is growing steadily in the life sciences industry as more organizations realize its value in unlocking process insights and driving transformative changes. As awareness increases and best practices are established, it is expected that more enterprises will incorporate process mining into their operations to stay competitive and achieve scalable transformation.

Applications of process mining across the life sciences value chain

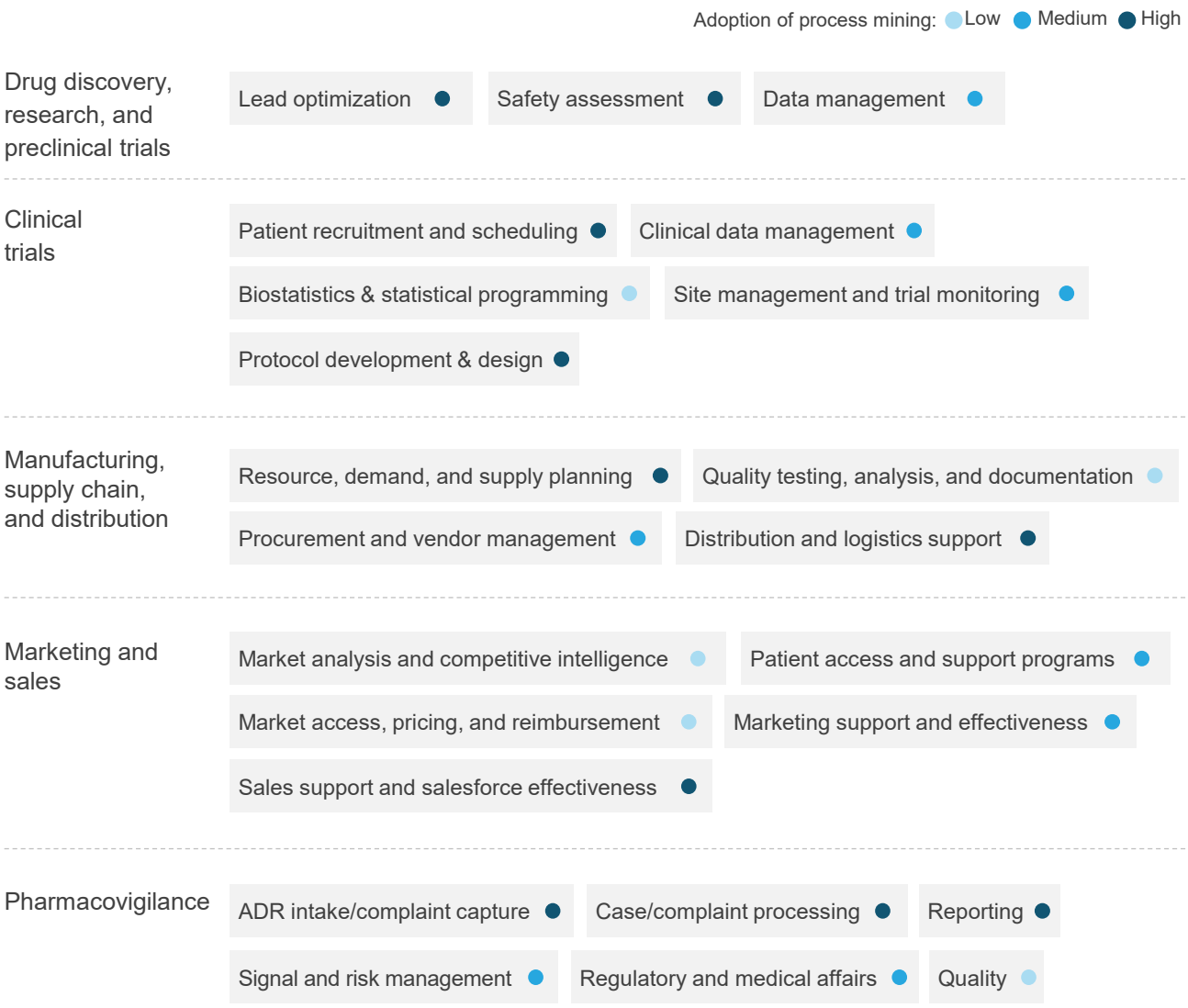
Organizations are increasingly using process mining to optimize and streamline both industry-specific processes and horizontal processes across the life sciences value chain. By leveraging process mining, life sciences companies can drive innovation, reduce costs, and accelerate time-to-market. These solutions are used across the value chain, including clinical trials, manufacturing and supply chain operations, and pharmacovigilance. They are highly adopted due to their ability to identify bottlenecks, optimize processes, improve adverse event reporting, and facilitate risk assessment, thereby enhancing the overall efficiency of these critical processes. Exhibit 4 illustrates the current level of process mining adoption across life sciences value chain.

> By adopting process mining, we were able to identify and eliminate inefficiencies, and improve process transparency. It was used to proactively address protocol deviations in preclinical trails, which resulted in cost reduction and improved compliance.
>
> – Executive Director – GBS Digital Services, Global pharmaceutical company

EXHIBIT 4

Adoption of process mining across the life sciences value chain

Source: Everest Group (2023)



Use cases of process mining across the life sciences value chain

Process mining is a technique that enables life science organizations to gain insights into their operational processes by analyzing data from existing enterprise systems. By operationalizing process mining, life science organizations can gain a better understanding of how their processes are performing and identify areas for improvement. This can benefit a range of use cases across the life sciences value chain, as discussed in Exhibit 5.

EXHIBIT 5

Process mining use cases across the life sciences value chain

Source: Everest Group (2023)

Use case/Objective	Business challenge	Solution
 Identifying and eliminating inefficiencies in the clinical trials process	• Challenges include data complexity, protocol deviations, and inefficient processes that impact the overall process time • Patient recruitment is a time-consuming process, which is marked by high attrition rates, delaying access to treatment	• Process mining can help identify the stages where recruitment is slower or determine bottlenecks to eliminate such inefficiencies in the trials process • It can monitor key metrics, such as the enrollment rate, protocol adherence, and patient retention rate, to reduce the overall trial duration
 Reducing deficiencies and improving efficiencies in the drug manufacturing process	• Drug manufacturing is a complex process to monitor, and it is difficult to streamline the production flow • Challenges with quality control in maintaining consistent raw material quality and equipment performance	• Process mining can help identify opportunities to optimize the inventory and enhance supplier management to reduce time-to-market • It can track key metrics, such as equipment utilization, batch yield, inventory levels, and production throughput rate, to enhance quality and efficiency
 Identify potential bottlenecks in pharmacovigilance	• Monitoring and assessing adverse drug reactions is a challenging and time-consuming process • Inefficient pharmacovigilance processes can result in delays in identifying and addressing safety issues, impacting patient safety and regulatory violations	• Enterprises can leverage process mining to identify bottlenecks and detect exceptions in adverse event reporting • Process mining can predict any delays in identifying drug safety issues with predictive monitoring capabilities • It can perform root-cause analysis to identify the causality of an adverse event
 Ensuring adherence to regulatory changes	• Enterprises need to be compliant with changing regulatory standards in the life sciences industry • Identifying non-compliant activities with manual techniques is a time-consuming process, and any delays in addressing non-compliance can have a financial impact	• Conformance-checking capabilities can help compare the discovered process with the industry-standard process flow to identify cases that do not comply with regulatory standards • Configure automated compliance checks and alerts can proactively identify and address process deviations to avoid penalties and regulatory overheads

Below we take a closer look at two use cases mentioned in Exhibit 5.

USE CASE 1

Identifying and eliminating inefficiencies in the clinical trials process

The clinical trial process is highly complex and regulated. As the trial progresses through complex stages, including intervention administration, data collection, and detailed analysis, the immense volume of data generated requires significant scrutiny to evaluate safety and efficacy. Companies must adhere to ethical and regulatory requirements during participant recruitment. Process mining can help at this stage in several ways.

Insights

- Process mining can assess the flow of activities, identify bottlenecks, and highlight inefficiencies in the clinical trial process
- It enables continuous monitoring of clinical trial activities, providing visibility into the trial progress and identifying potential issues as they arise
- Enterprises can leverage process mining to analyze resource utilization patterns and identify automation and optimization opportunities in the clinical trials process

Actions

- Process mining can streamline the recruitment stage by optimizing participant screening steps and implementing automated workflows to accelerate participant enrollment
- It can configure rules to push proactive alerts so that enterprises can address any issues, make necessary adjustments, and ensure the trial progresses to plan

USE CASE 2

Reducing deficiencies and improving efficiencies in the drug manufacturing process

Drug manufacturing involves complex processes with numerous steps, making it challenging to monitor and optimize the entire production flow. Maintaining a consistent quality of raw materials and equipment is crucial, as any variations can impact the manufacturing process and final product quality. The supply chain involves multiple stakeholders, processes, and handoffs, making it challenging to manage and optimize the flow of materials and products. Process mining can help in several ways.

Insights

- Process mining can visualize the end-to-end drug manufacturing process and identify process loops, bottlenecks, and deviations by mining the log data from different ERP, CRM, and SCM systems, and the data collected from IoT devices
- Enterprises can use the conformance-checking capability to compare the discovered as-is process and benchmark it with industry best practices to identify any non-conformant cases

Actions

- The sequence of supply chain activities can be optimized to minimize wait times and delays by understanding the impact of different what-if scenarios on the overall process
- Predictive monitoring can help anticipate maintenance issues, helping to proactively address potential problems and reduce equipment downtime

Process mining adoption challenges and best practices

Challenges in adopting process mining at scale

Scaling process mining initiatives is not an easy task. Exhibit 6 illustrates some common challenges that organizations face when adopting process mining at scale.

EXHIBIT 6

Common challenges in adopting process mining at scale

Source: Everest Group (2023)

Limited data availability

- Extracting event log data in the correct format from non-standard IT systems
- In geographies with low penetration of enterprise systems, the availability of event log data for process discovery is a key challenge

Data security risks

- Data security concerns hinder third-party access, impacting collaboration and insights sharing
- Time-consuming approval process hampers timely access to event logs data

Siloed approach

Within enterprises, different business units or teams (e.g., process excellence, automation CoEs) may carry out process mining projects in silos and with limited support

Transparency of operations

Resistance to the adoption of process mining due to reservations about increased transparency and visibility into the ways of working

Lack of technology awareness

Lack of stakeholder buy-in due to a limited understanding of process mining technologies, their applications, and their benefits (e.g., comparing them with a BI tool, unrealistic RoI expectations)

Addressing these challenges requires careful planning, stakeholder engagement, and ongoing support from organizational leadership. Organizations should anticipate these challenges, develop careful strategies, and follow best practices to overcome them as they scale their process mining initiatives.

Best practices to scale process mining initiatives

The following best practices can help enterprises to successfully implement process mining and maximize the benefits from their investments:

- Secure buy-in from enterprise leadership and IT: To foster a culture of continuously identifying process mining opportunities and ensuring data security and compliance, enterprises must obtain buy-in from their leadership and relevant IT stakeholders
- Start with a simple project: Begin with a structured process that has few steps and requires minimal data preparation. Secure initial results quickly to build trust and expedite adoption. Learn from the pilot project to refine your approach and identify any challenges or limitations
- Collaborate with business units and Centers of Excellence (CoEs): Foster collaboration and open communication with business units, process excellence teams, and automation CoEs to gather insights and drive process improvements. Additionally, having a dedicated multidisciplinary team for process mining initiatives ensures accountability, expertise, and continuity in your scaling efforts
- Develop an effective change and talent management program: A change management program, supported by appropriate training and resources to the employees involved in the process mining initiatives, can help build a skilled workforce that ensures the successful adoption of such initiatives
- Select an enterprise-grade solution: Select a process mining software that meets your organization's requirements and capabilities. Assess various tools based on their features, scalability, usability, and compatibility with your current systems
- Ensure data governance: Continuously monitor data governance practices, including data integration, standardization, security, and privacy, to ensure compliance and smoother data transformation. Conduct periodic data governance audits to assess the effectiveness of data management and address any issues or gaps
- Increase technology awareness: Spread awareness about the process mining technology and its advantages to address transparency issues and share success stories

Scaling process mining initiatives is an iterative process. Learning from your feedback, adapting to the changing needs of your organization, and continuously refining your approach are crucial to achieve long-term success from these initiatives.

> Getting early buy-in from the executive team, starting with a small project and achieving quick wins, and ensuring the IT team is on board are some of the best practices for scaling process mining adoption.
>
> – Executive Director – GBS Digital Services, Global pharmaceutical company

Conclusion

The life sciences industry is undergoing a phase of rapid transformation after the pandemic. Growing data volumes, macroeconomic factors, and complex regulatory norms have compelled life sciences enterprises to adopt intelligent automation. Additionally, life sciences organizations are rethinking their priorities and objectives, which has driven them to increase their investments in R&D and pivot to digital operations strategies. The pandemic has further emphasized the need for digital transformation in the industry, as the lack of process visibility and transparency poses a significant hindrance to achieving scalable transformation.

In recent times, process mining has emerged as a valuable solution to accelerate digital transformation across industries, including life sciences, by driving efficiency and optimization. It can help address the challenges with complex processes across the life sciences value chain, including clinical trials, drug manufacturing, pharmacovigilance, and adherence to regulatory norms. By leveraging process mining, life sciences organizations can gain valuable insights into their processes across the value chain and effectively identify and address bottlenecks and inefficiencies. The adoption of process mining can help improve clinical trial efficiency and reduce deficiencies in drug manufacturing. By embracing process mining and leveraging its capabilities, organizations can unlock numerous benefits, including improved cash flow for R&D, faster time-to-market, and enhanced supply chain efficiency.

The successful adoption of process mining requires addressing the challenges head-on and implementing best practices to drive superior outcomes and position life sciences organizations for long-term success in an ever-evolving industry.

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