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Intelligent Automation, Fueling the Transformation of **Pharmacovigilance**

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Table of Contents

CLICK ANY HEADING TO NAVIGATE DIRECTLY TO THAT PAGE.

IDC Opinion

Growth in the number of products under development and in the market is resulting in a significant escalation in case volumes. The rapid influx of diverse data sources and the need to have a centralized overview of the dynamic and evolving global regulations have created immense pressure on leaders of pharmacovigilance (PV) organizations. The COVID-19 pandemic not only resulted in an explosion in the number of Individual Case Safety Reports (ICSRs) but highlighted that it was possible and necessary to have ever more complex trials, with products in multiple states in different markets, blurring the boundaries between clinical and marketed products and the monitoring and management of adverse events (AEs).

These needs are exerting pressure to modernize existing safety systems, which often represent siloed information systems that were primarily designed to drive efficiencies in traditional, manual case processing. With case volumes growing at 10%–15% per year, significant portions of PV budgets are allocated to the transactional aspects of case intake and processing. Therefore, the primary goal of platform modernization is usually to reduce these costs while further improving efficiencies by automating these processes using technologies such as robotic process automation (RPA). Yet, attempting to upgrade traditional siloed solutions can result in a disproportionate increase in costs versus benefits gained. As it is, PV is seen as a cost center, and this poses additional challenges.

PV IT and business leaders are struggling to flip this over, positioning PV not as a cost center but as a value-add to the business.

This requires the adoption of newer technologies such as generative AI, ML, and natural language processing (NLP). These cognitive technologies should be leveraged to build intelligent next-generation learning systems that mitigate risk, strengthen compliance, and improve patient outcomes. Existing platforms need to move beyond the transactional rule-based parts of case intake and processing with a focus on driving efficiencies and cost savings. They need to transition to modern versions of platforms that shift the paradigm from a reactive approach of assessing the causality of an event to a proactive one that powers real-time signal detection and predicts the likelihood of an adverse event. This should thus proactively preempt the occurrence of AEs based on an understanding of the molecule and the patient's profile, help fine-tune prescribing patterns, and truly fuel precision care. This is when the true value that PV brings to the table will be recognized.

To get a sense of where organizations lie on the maturity curve in their PV automation journey, IQVIA commissioned a survey and study from IDC. Based on IDC's findings, it is evident that the industry is in a hurry to adopt and implement PV automation initiatives. Various players are at different stages in their journey. While about one-third of the organizations surveyed fell into level 1 (emerging) and half belonged to level 2 (transforming), only one-fifth belonged to level 3 (maturing). The IDC survey data indicates that the metrics that these organizations were using to measure ROI on PV automation initiatives were linked primarily to business outcomes rather than to business operations. The industry is clearly moving toward adopting advanced automation technologies, with over one-third indicating that they have used generative AI in their completed drug safety workflow initiatives.

Organizations often lack the maturity to drive safety automation and rush head-on into the digital transformation of their PV business without a clear strategic vision. But driving intelligent automation requires an assessment of multiple aspects, including:

- Addressing the why — baselining the current status and evaluating short-term goals and long-term strategic objectives
- Identifying key stakeholders from line of business and from IT
- Determining the impact on costs and on workflows to drive the desired change
- Establishing a center of excellence (COE) and determining needs for upskilling internal teams
- Identifying metrics to measure ROI and identifying low-hanging fruit to demonstrate success
- Identifying partners not only to implement but to guide this change — from a technology perspective, from a business operations perspective, and from a change management perspective
- Assessing budgets and prioritizing use cases

The survey indicated that only 11% of the industry is partnering with vendors to identify use cases. This is a significant gap, as use case identification was the second most important concern (36%) for the industry after regulatory concerns (48%). This is understandable, as 30% of the industry reported finding a partner of choice as a key concern. Partners will play a key role in working alongside pharma, not only in identifying key use cases but also in defining the right technology mix and delineating workflows.

The commitment to PV automation is there, with half of the industry investing 1 million to 5 million (in U.S. dollars, euros, or U.K. pounds equivalents) on PV automation and 17% investing 5 million to 20 million (in U.S. dollars, euros, or U.K. pounds equivalents). Almost one-third of the industry sees this spend increasing by 5%–10% in the next two years. With 12% of the IT budget committed to PV automation initiatives, it is very important that organizations transition from level 1 (emerging) players that are in initial stages of dabbling with PV automation and level 2 (transforming) players that are implementing bits and pieces of automation, leveraging some level of modern tech, to level 3 (maturing) players that are moving toward end-to-end implementation of PV automation across the PV value chain, leveraging the right portfolio of modern automation technologies, including generative AI, and have robust governance models and well-defined metrics in place.

IN THIS WHITE PAPER

This white paper describes highlights of an IDC global online survey on the topic of automating drug safety surveillance, commissioned by IQVIA. Survey respondents included senior professionals who were primarily decision makers involved in management and investment decisions related to PV strategy and the automation of drug safety surveillance.

Demographics of survey respondents are available in the Appendix. IDC was able to identify a maturity scale using positive correlations across dimensions of PV metric outcomes and business outcomes. Three groups of respondents were created across the scale to enable the evaluation of characteristics that identify how organizations can improve the maturity of drug safety surveillance initiatives to deliver better business outcomes. Details on the method used to create the scale are available in the Appendix.

Drivers and Challenges for PV Automation

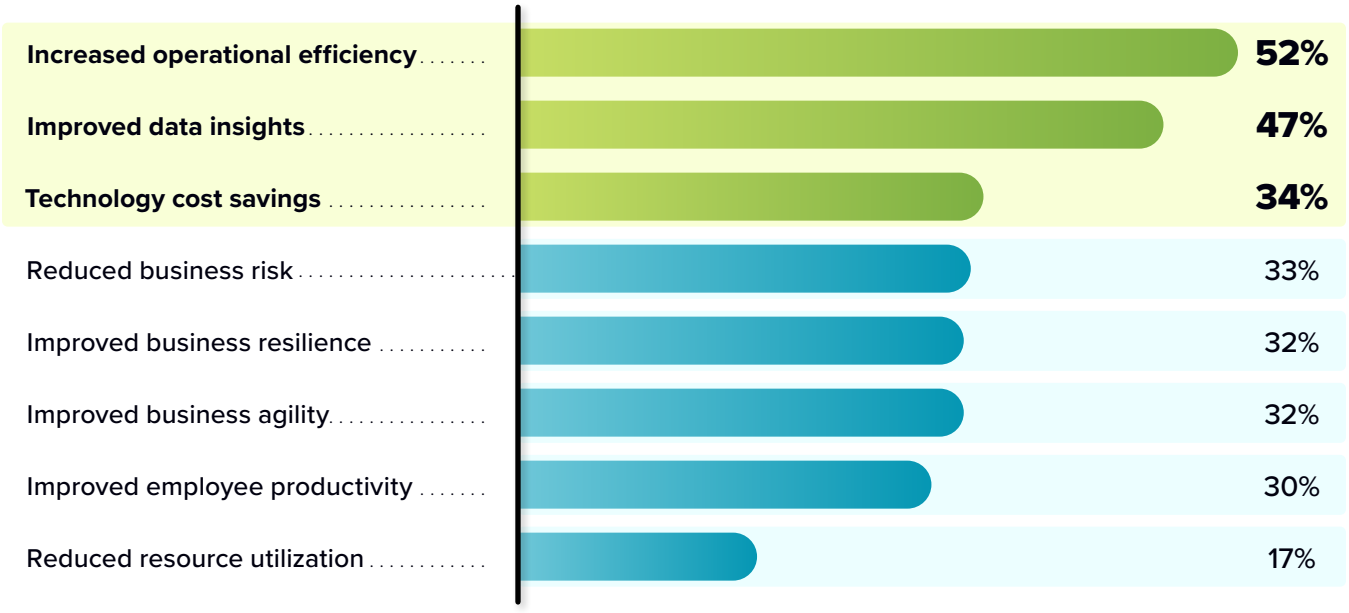
There is a rapidly growing interest in the life science industry to scale automation in PV. The desire to drive operational efficiency clearly topped the list with 52% of the industry, indicative of both the cost pressures that the industry is facing today and the need to be able to handle ICSRs at scale. Following closely was the need to drive data insights (47%), followed by cost savings (see **Figure 1**).

FIGURE 1

Key Drivers for PV Automation

What were the three most important business outcomes that organizations were trying to achieve by investing in PV automation in the past year?

(% of respondents)



See Appendix for source information.

The implementation of PV automation requires a partner that has a deep understanding of the varying regulations and a platform that can adapt to and address these diverse requirements.

Managing business risk, ensuring resilience, and driving business agility are all lessons learned from the COVID-19 pandemic, where all of these became priorities. There was no time to be lost to bring the vaccines to market, and agility needed to be complemented by ensuring patient safety and business continuity.

Despite the clear benefits of PV automation, the industry is concerned about ensuring regulatory compliance (48%). Pharma is a highly regulated industry, and compliance is a top priority. While one wants to drive efficiency, there is a critical need to ensure that compliance with varying regulations across geographies is ensured. This requires complying not only with Good Pharmacovigilance Practices, FDA guidelines, and European Union (EU) PV legislation but with regulations across the globe. In addition, care needs to be taken to ensure compliance with regulatory requirements regarding data security, privacy, and data sovereignty. This has also triggered a lack of trust (27%) in the ability of PV automation solutions to deliver on these fronts (see **Figure 2,** next page).

Hence, the implementation of PV automation requires a partner that has a deep understanding of these varying regulations and a platform that can adapt to and address these diverse requirements.

The presence of a well-established governance model to drive implementation strategy is reflective of maturity in the safety automation process. And while a lot of the industry desires to acquire a high level of maturity, it is cognizant of the fact that it is currently does not have the desired governance models in place, triggering concerns (32%) and flagging the need to find a partner of choice (30%) to move the needle. A lack of internal skills and a lack of market solutions also present challenges.

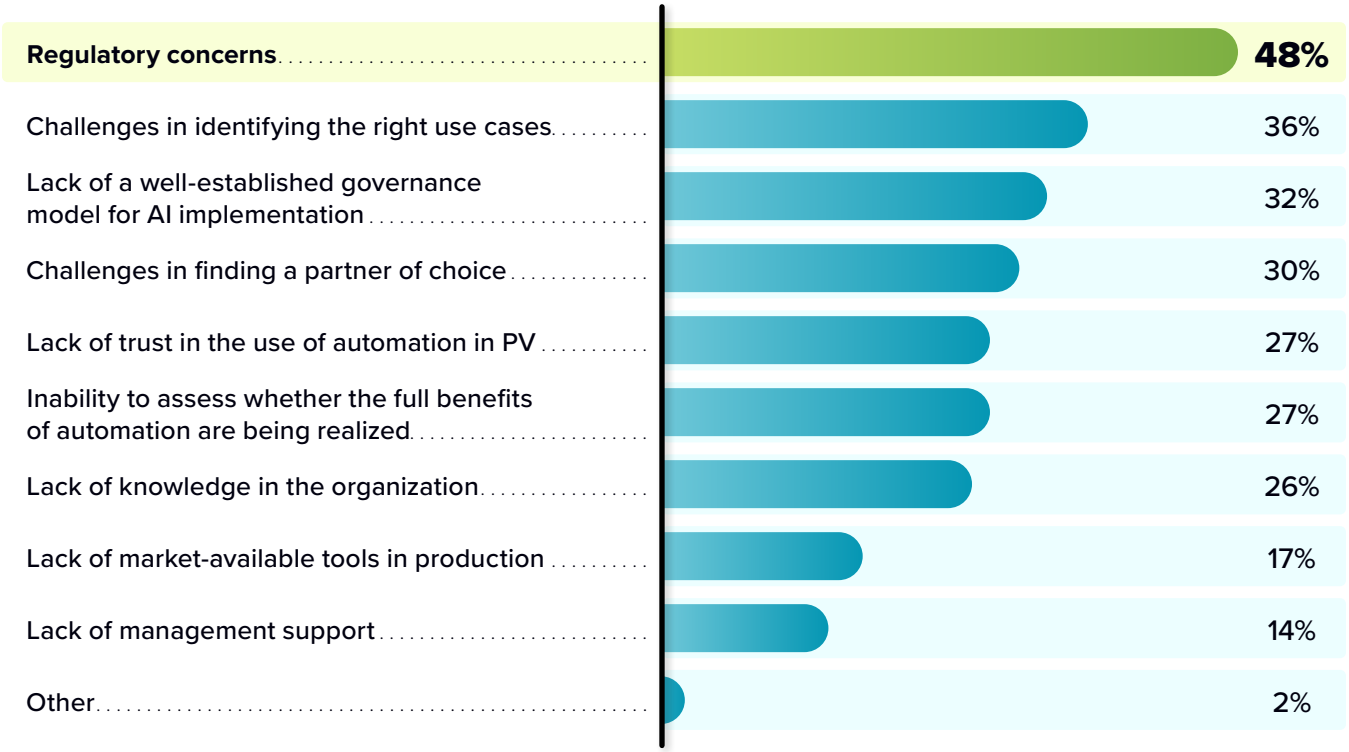
Despite the clear benefits of PV automation, 48% of the industry **is concerned about ensuring regulatory compliance.**

FIGURE 2

Key Challenges for Driving PV Automation

What were the key challenges faced by organizations in implementing PV automation?

(% of respondents)



See Appendix for source information.

The presence of a well-established governance model to drive implementation strategy is reflective of maturity in the safety automation process.

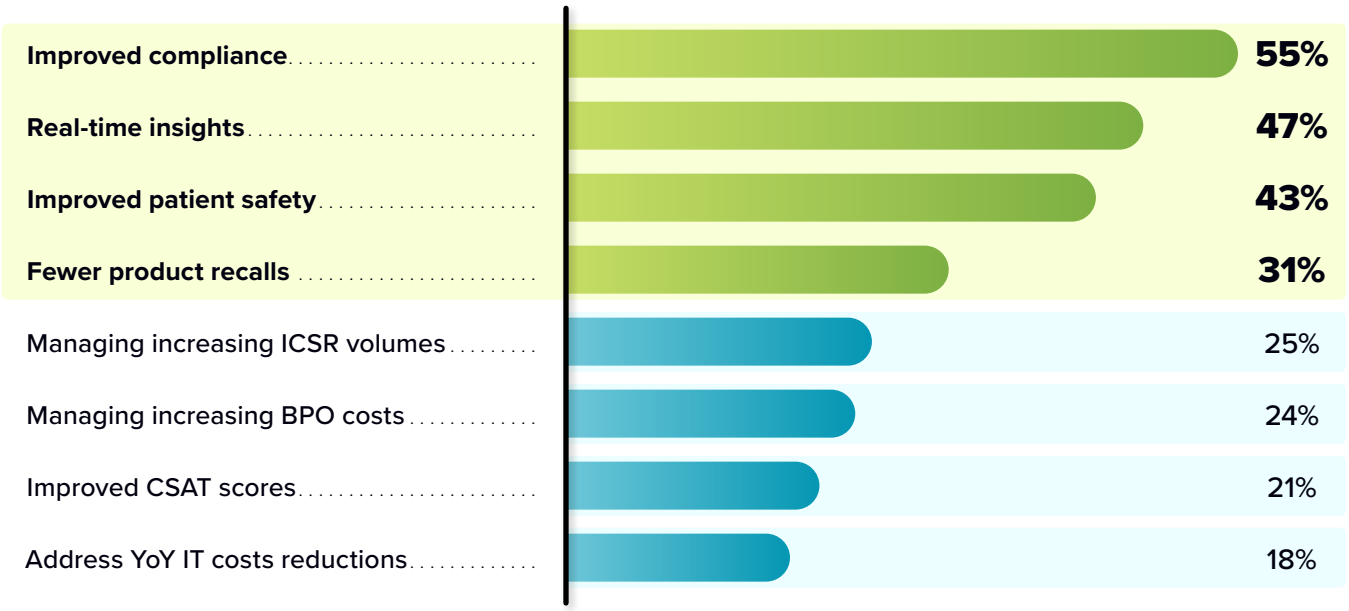
Defining Key Metrics to Determine ROI in PV Automation

It is essential to predefine metrics to measure success on investments made in scaling automation in PV. Compliance, once again, comes out at the top (55%), indicative of the key focus of the life science industry on this topic. Real-time insights (47%) ranked second, demonstrating the urgency of garnering insights to drive patient safety (43%). The focus is also on business outcomes, with fewer product recalls ranking fourth (31%). Notably, cost reduction ranks last in the list of metrics (see **Figure 3**).

FIGURE 3

Key Metrics for Measuring ROI in PV Automation

Which of the following are the most important metrics that your organization uses to assess performance related to investments in implementing automation in PV?
(% of respondents)



See Appendix for source information.

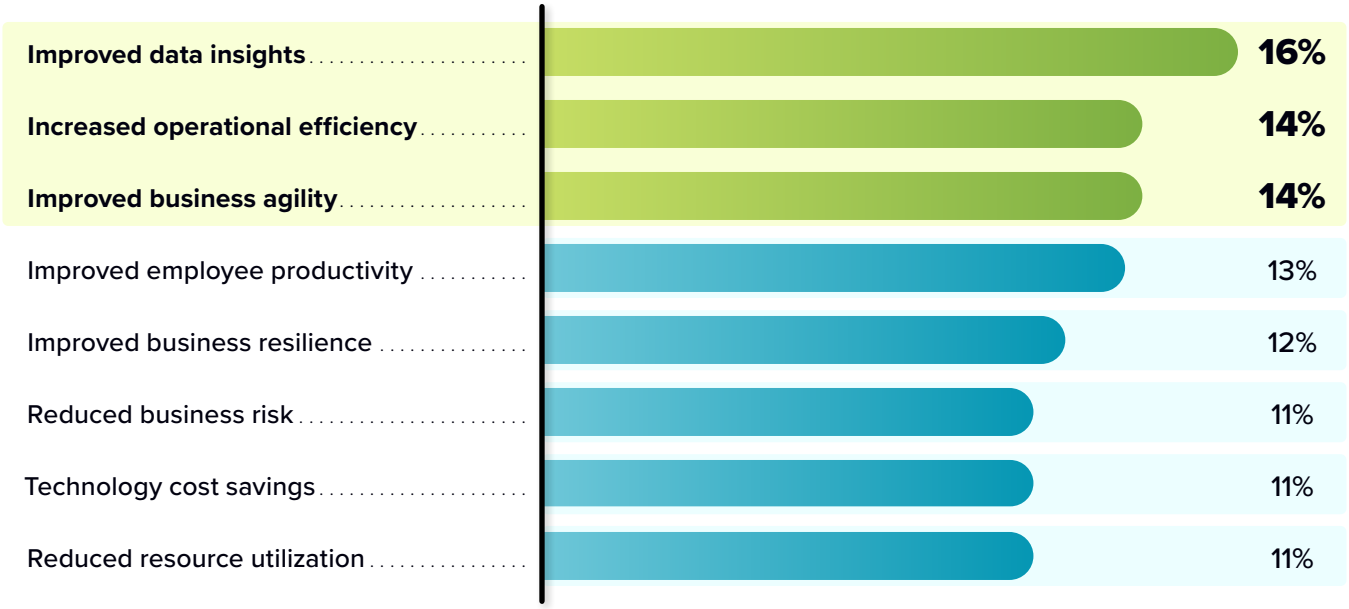
PV Business Operations

While there was an intent to track certain metrics to measure the success of PV automation, it is interesting to note that improved data insights (16%) followed by operational efficiency (14%) and improvement in business agility (14%) were the top 3 areas where the maximum benefits were gained in the past year (see **Figure 4**).

FIGURE 4

Improvement Seen in Business Operations

What annual percentage change has your organization seen in the past 12 months for the criteria listed below?
(% of respondents)



See Appendix for source information.

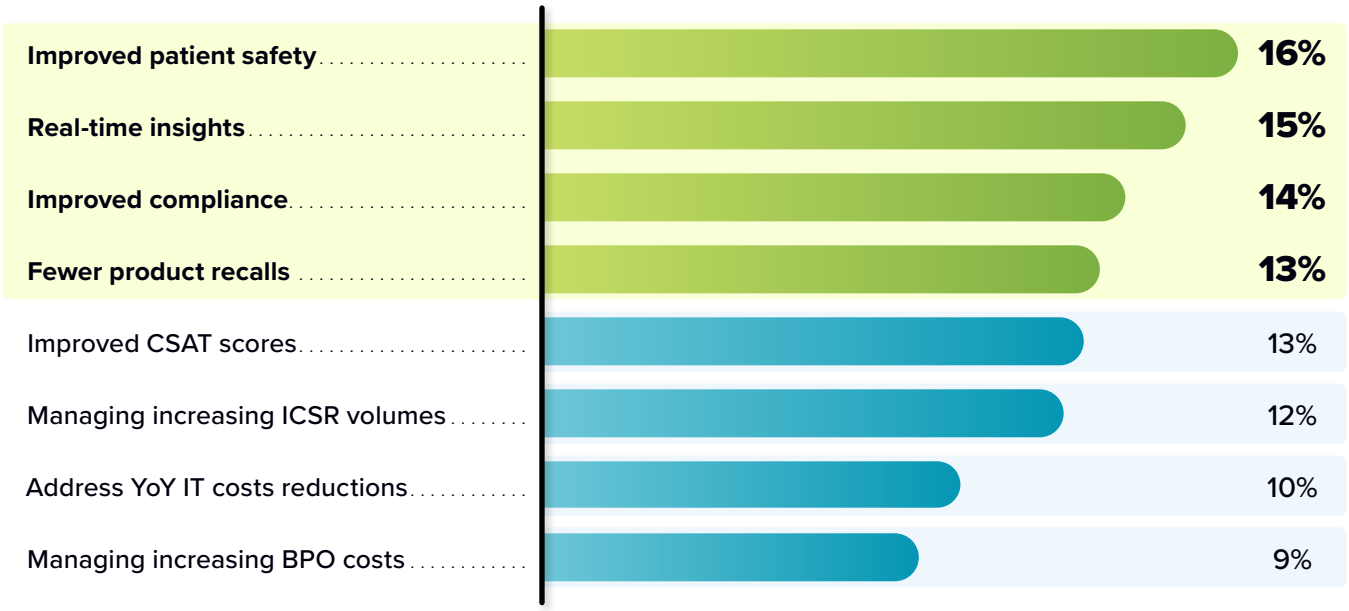
Business Outcomes

It is very evident that while operational efficiencies are important, PV automation is driven by key business outcomes, including improved patient safety (16%), followed by real-time insights (15%), improved compliance (14%), and fewer product recalls (13%). Patient safety is a priority, and that is where the maximum gains are seen. However, almost the same level of improvement is seen across all of these criteria. Gains to the order of about 15% are significant, justifying the keen interest in investing in PV automation that is seen in the life science industry today.
A 13% reduction in product recalls can drive huge benefits for a pharma company, in terms of both cost benefits and brand value, as this is a matter of credibility for the company. These are goals that level 3 (maturing) organizations will pursue (see **Figure 5**).

FIGURE 5

Improvement Seen in Business Outcomes

What annual percentage change has your organization seen in the past 12 months for the criteria listed below?
(% of respondents)



See Appendix for source information.

Assessing Maturity in PV Automation

As the life science industry struggles to achieve maturity in the PV automation space, multiple factors come into play. These include the technologies leveraged, governance models, establishment of centers of excellence, funding, number of ongoing PV automation initiatives, and partner selection.

This survey attempts to dig into these factors and determine where the industry stands in its PV automation journey.

Technologies Being Leveraged in PV Automation

Diverse technologies are being used to drive PV automation, including interpretive AI, predictive AI, generative AI, machine translation, NLP, and robotic process automation:

- **RPA** is a software technology that makes it easy to build, deploy, and manage software robots so that they emulate humans' actions and automate repetitive tasks performed by them and is governed by business logic and structured inputs.
- **NLP** is a ML technology that gives computers the ability to interpret, manipulate, and comprehend human language.
- **Machine translation** (MT) uses ML models to automatically translate text or speech from one language to another.
- **Interpretive AI** interprets images or data streams and generates insights to drive meaningful actions.

- **Predictive AI** analyzes large training data sets to identify long-term patterns in behavior and helps predict changes in behavior.
- **Generative AI** is a branch of computer science that involves unsupervised and semi-supervised algorithms that enable computers to create new content using previously created content such as text, audio, video, images, and code in response to short prompts.

Medical ontology–enabled NLP/ML has been used to map relevant ICSR information to International Conference on Harmonization E2B data fields in a regulatory-compliant manner, significantly reducing data capture efforts. NLP has been used by the FDA to classify AEs identified in ICSRs as possible anaphylaxis after H1N1 influenza vaccination. This was the first application of AI to PV by the FDA.

RPA has been extensively applied in PV. Use cases range from AE data entry, triaging of reports, screening of literature, analysis of PV databases for signal detection, narrative generation, aggregate report generation, and SAE data reconciliation to the compilation and submission of safety reports, to name a few.

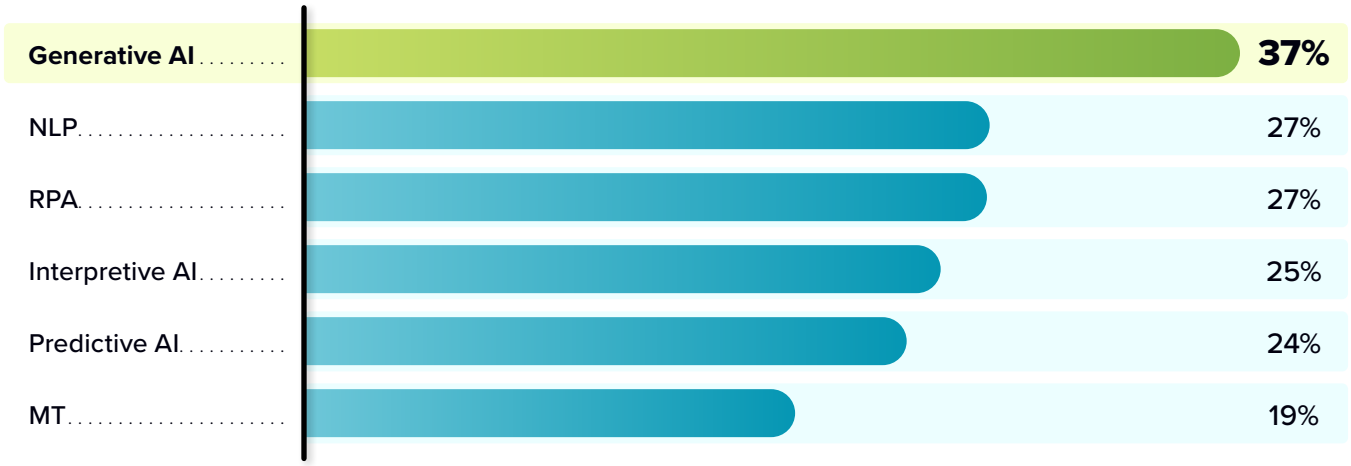
Yet the survey findings very interestingly indicated that 37% of the respondents have used generative AI in their completed drug safety workflow automation initiatives. Despite being an emerging technology, the fact that generative AI topped the list while NLP (27%) and RPA (27%) came next is indicative of the speed at which the industry is adopting generative AI and the value it sees in it (see **Figure 6,** next page). Level 3 organizations will try to rapidly adopt modern technologies, such as generative AI, and embed them within their PV automation initiatives.

FIGURE 6

Key Technologies Used to Drive PV Automation

What percentage of completed drug safety workflow automation initiatives have you used for each of these automation technologies?

(% of respondents)



See Appendix for source information.

Despite being an emerging technology, the fact that generative AI topped the list while NLP and RPA came next is indicative of the speed at which the industry is adopting generative AI and the value it sees in it.

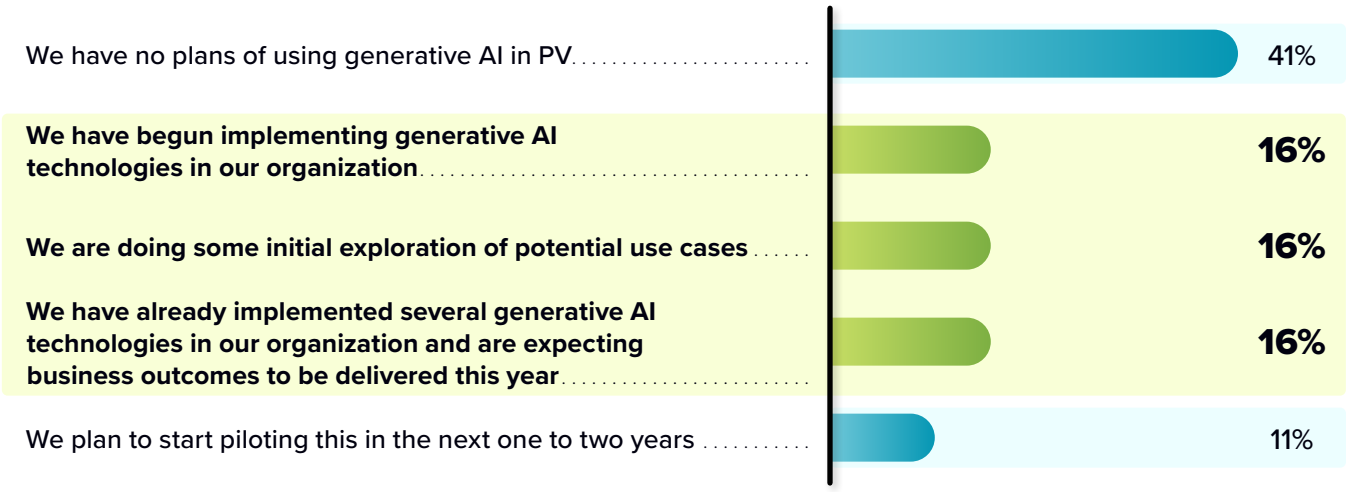
Industry Adoption of Generative AI

While the previous data indicated that the industry was in a hurry to embed generative AI in PV automation initiatives, further data shows that only 16% of the industry has already implemented generative AI technology, 16% is exploring use cases, and 16% has begun the implementation of generative AI within the organization (see **Figure 7**). This suggests that while 37% of the industry reported that it has included generative AI in its completed drug safety workflow automation initiatives, these are still early days, and generative AI may have actually represented only a small component of more than one technology that was used to drive PV automation. These results may be more reflective of the need for everyone to be seen to be using generative AI. To conclude, while these are still early days for the adoption of generative AI in PV, there is clearly a heightened interest in it, and it is set to grow.

FIGURE 7

Industry Adoption of Generative AI to Drive PV Automation

What is the current approach to generative AI to drive automation in PV in your organization?
(% of respondents)



See Appendix for source information.

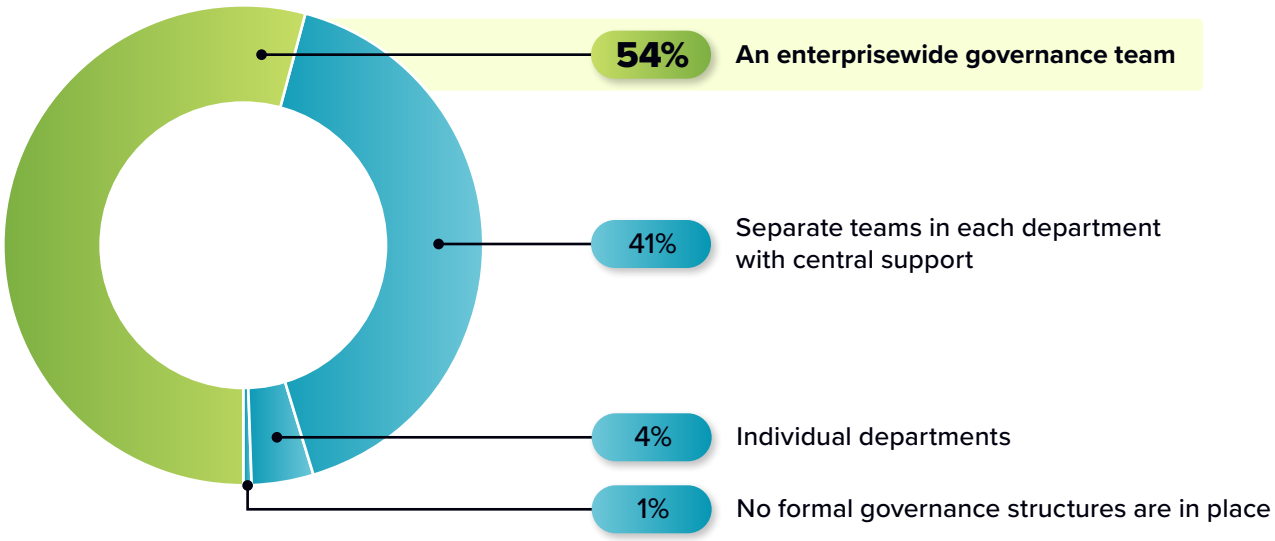
Governance Models for PV Automation

More than half of the industry (54%) indicated that it has an enterprisewide governance team in place to drive PV automation initiatives, while the rest of the industry has primarily implemented a federated model. Considering the growing number of technologies and the compliance issues involved, as well as associated budgetary implications, an enterprisewide governance model would be recommended. Establishing a robust governance model is a key indicator of a level 3 organization, where use cases are identified and the technology mix is defined in a well-orchestrated manner (see **Figure 8**).

FIGURE 8

Governance Models for PV Automation

Who makes the decisions on new automation initiatives?
(% of respondents)



See Appendix for source information.

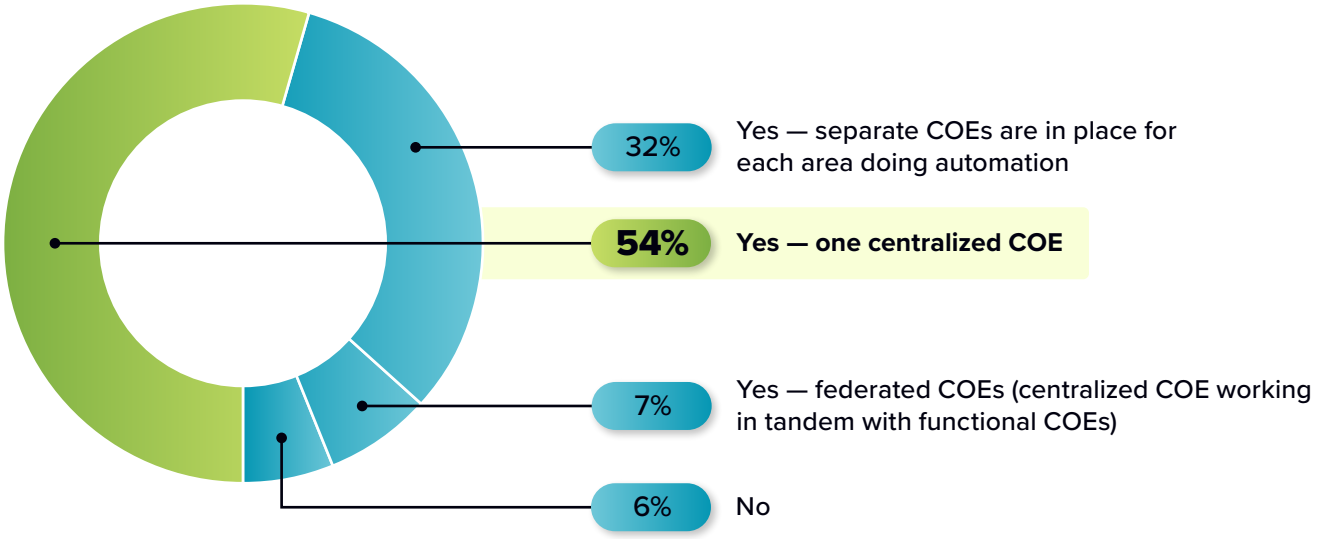
Establishing a Center of Excellence for PV Automation

While 54% of the life science industry has an enterprisewide governance model for driving its automation initiatives, the same percentage also maintained a centralized COE — suggestive of an overarching strategy toward adopting centralized models. Yet only 7% adopted a federated COE model and one-third had separate COEs for each area of automation. While a centralized model makes sense to build an overarching COE with core expertise in all the automation technologies, each functional area is indeed unique. Hence, building out functional area-specific COEs holds significant value (see **Figure 9**).

FIGURE 9

PV Automation COEs

Does your organization have an automation COE in place?
(% of respondents)



Note: Total will not sum to 100%. See Appendix for source information.

Ongoing PV Automation Initiatives

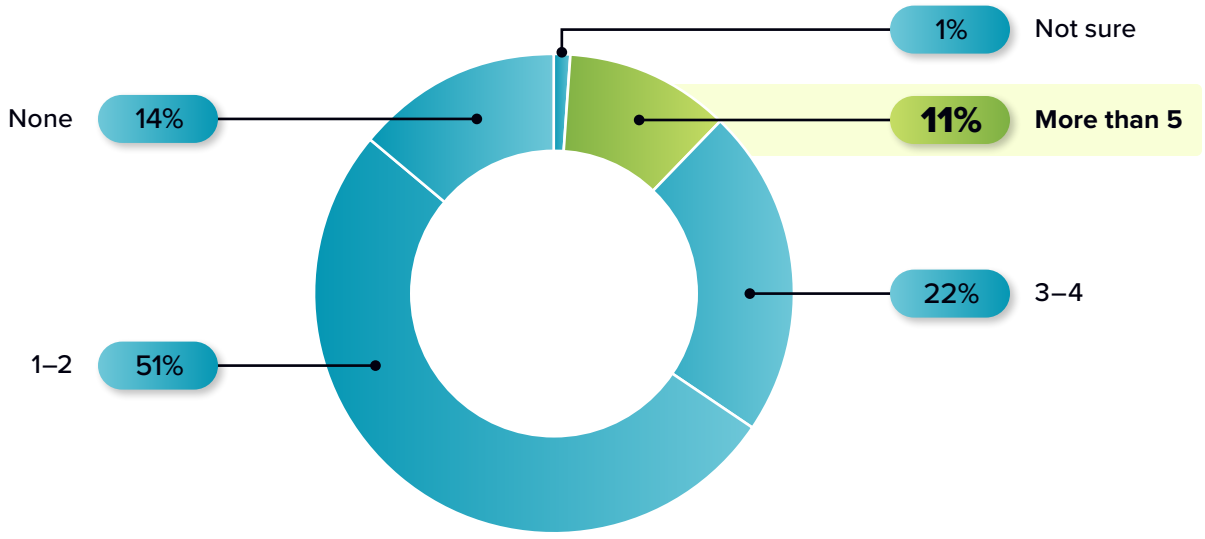
Half of the industry (51%) has one or two ongoing PV automation initiatives. This is clearly reflective of an industry that recognizes the importance of the need to automate to drive efficiencies, to drive faster results, to drive deeper insights, and to save costs.

Notably, one-fifth of the industry has three or four ongoing PV automation initiatives, and over 10% had more than five ongoing PV automation initiatives. This is very significant. This also calls for the need to establish mature models and to identify partners with significant domain and technical expertise to help orchestrate these multiple initiatives (see **Figure 10**).

FIGURE 10

Number of Ongoing PV Automation Initiatives

How many PV automation projects is your organization currently running or has it run in the past 12 months? (% of respondents)



Note: Total will not sum to 100%. See Appendix for source information.

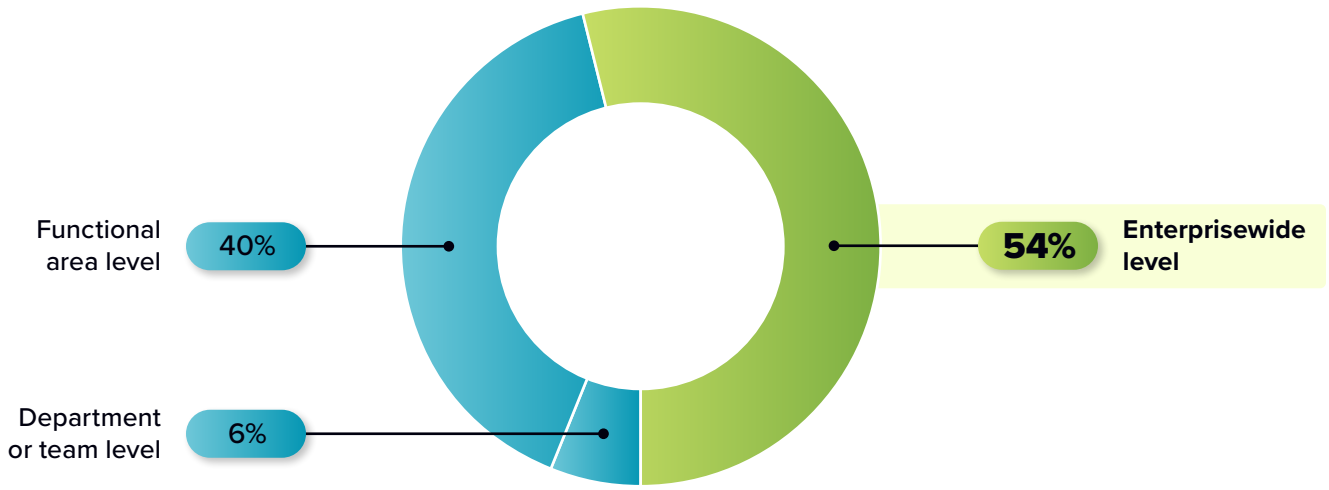
Funding Decisions, Budgets, and IT Spend on PV Automations Initiatives

One sees varying strategies on decision-making regarding funding for PV automation initiatives, with 54% keeping decision-making at an enterprise level. This aligns with the governance model strategy as well. However, 40% of funding decisions are still kept at a functional level (see **Figure 11**).

FIGURE 11

Driving Funding Decisions for PV Automation Initiatives

At what level are most decisions about which new automation initiatives to fund made?
(% of respondents)



See Appendix for source information.

IT spend on PV automation initiatives is expected to remain fairly consistent over the next two years and represents approximately 12%–13% of the IT budget (see **Figure 12**).

FIGURE 12

IT Budget Invested on PV Automation Initiatives Now and in the Next Two Years

What percentage of your organization's budget is invested on PV automation initiatives now and in the next two years?
(% of respondents)

See Appendix for source information.

Half of the industry spent 1 million to 5 million (in U.S. dollars, euros, or U.K. pounds equivalents) on PV automation initiatives, but 17% spent 5 million to 20 million (in U.S. dollars, euros, or U.K. pounds equivalents), probably representative of key strategic initiatives from big pharma.

Biotechs and smaller pharma probably represent the 29% of the industry that spent less than 1 million (in U.S. dollars, euros, or U.K. pounds equivalents) on PV automation initiatives (see **Figure 13,** next page).

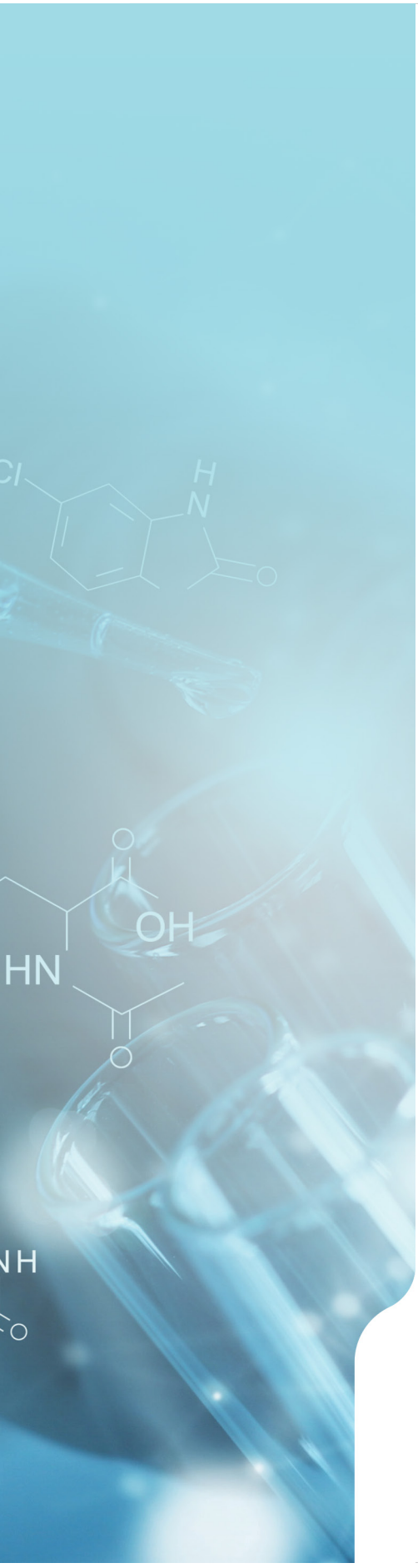
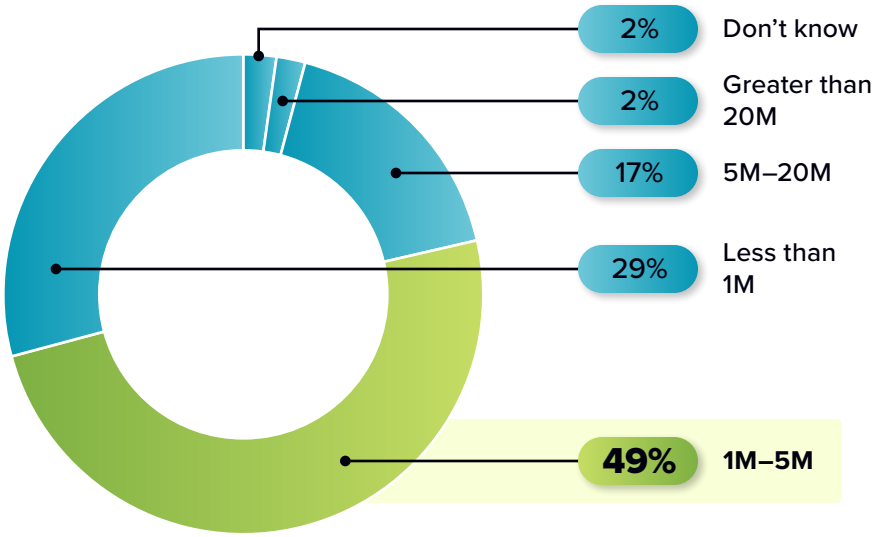


FIGURE 13

Net Organizational Spend on PV Automation Initiatives

What is your organization's current annual spend on PV automation technology (in U.S. dollars, euros, or U.K. pounds equivalents)?
(% of respondents)



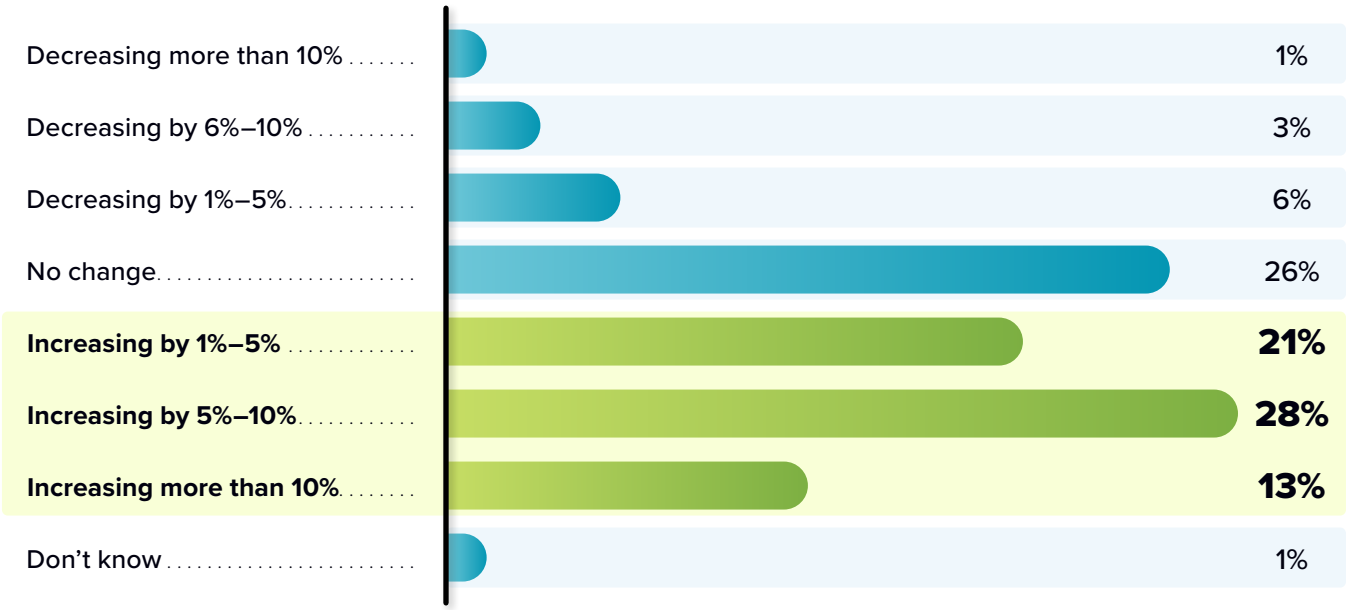
Note: Total will not sum to 100%. See Appendix for source information.

It has become an automation-hungry universe, with two-thirds of the industry planning on increasing its spend on PV automation initiatives, with 13% increasing it by more than 10%, as indicated in **Figure 14.**

FIGURE 14

Increase in Spend on PV Automation Initiatives in Two Years

How do you see the current spend on PV automation technology changing in the next two years?
(% of respondents)



See Appendix for source information.

Maturity Levels in PV Advanced Automation — Current and Future

Maturity Levels Across PV Operations

Current

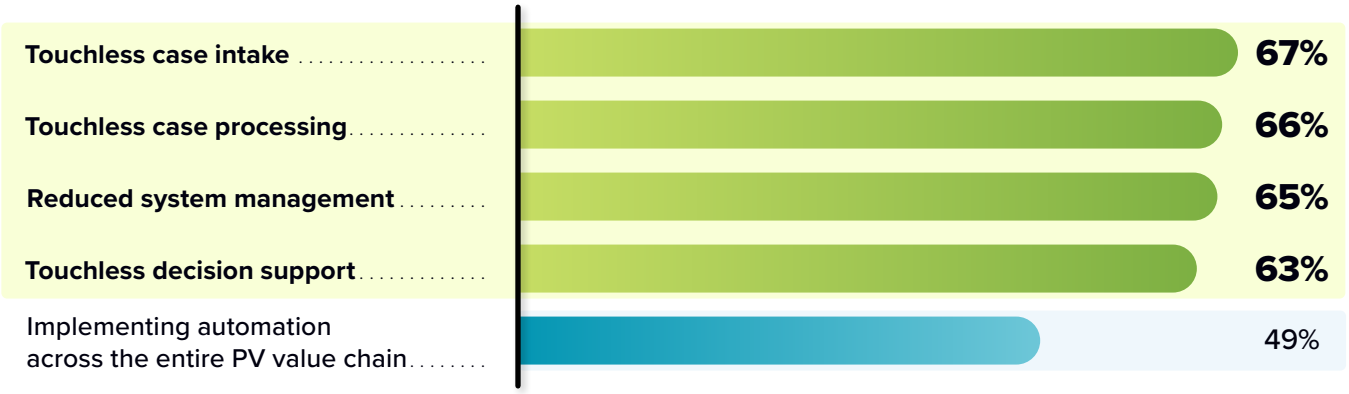
Two-thirds of the industry believes that it has made good progress when it comes to touchless case intake, touchless case processing, touchless decision support, and reduced system management using advanced PV automation techniques (beyond RPA). About half of the industry believes that it has achieved some success in implementing automation across the entire PV value chain (see **Figure 15**).

FIGURE 15

Progress in Using Advanced Automation Technologies (Beyond RPA) for PV

Overall, how far along do you estimate your organization is in using advanced automation (beyond RPA) in these processes?

(% of respondents)



See Appendix for source information.

Future

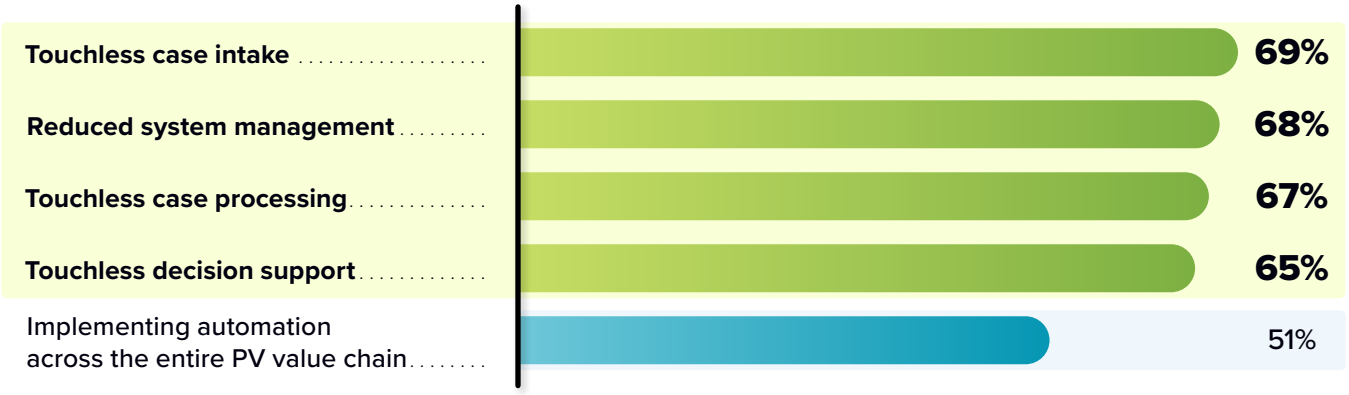
Over the next two years, the industry expects to have made only marginal progress in using advanced PV automation techniques (beyond RPA). About half of the industry believes that it has achieved some success in implementing automation across the entire PV value chain. This implies that it will take some time to fully leverage advanced automation technologies for PV automation (see **Figure 16**).

FIGURE 16

Progress in Using Advanced Automation Technologies (Beyond RPA) for PV in the Next Two Years

Over the next two years, how far along do you estimate your organization will be in automating the workflows associated with these drug safety system objectives?

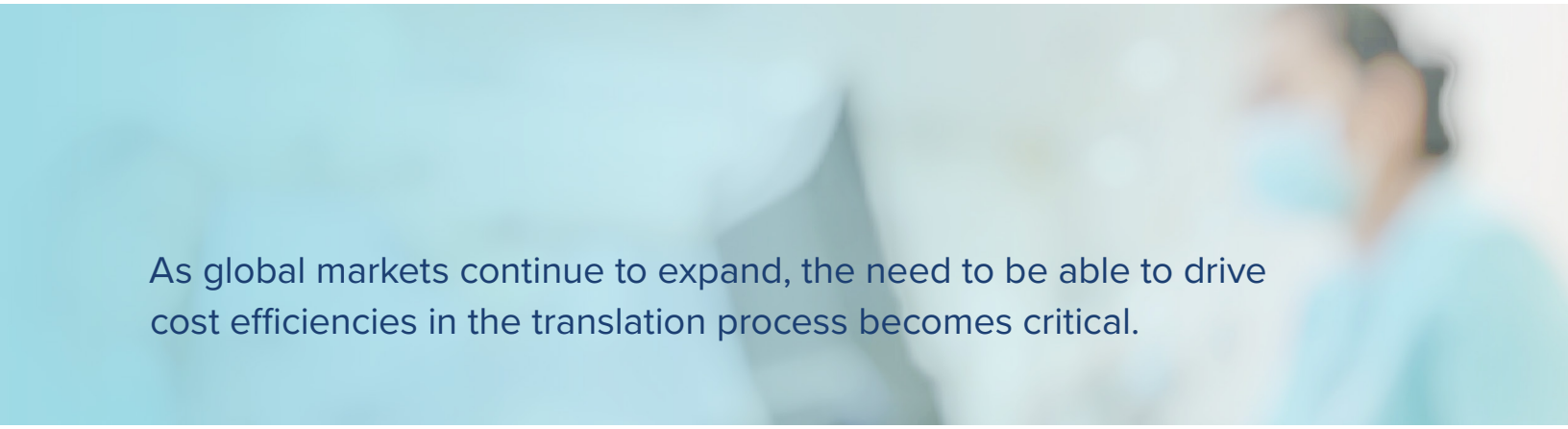
(% of respondents)



See Appendix for source information.

Maturity Levels in Case Intake and Case Processing

Two-thirds of the industry believes that it has made a lot of progress in terms of automating case intake and case processing across all use cases. While this may more be the case with respect to case intake, a lot still needs to be done in areas such as signal detection, event identification, and causality assessment when it comes to case processing. Certain transactional tasks within these processes may have been automated, but it would be wrong to conclude that end-to-end automation has been accomplished. There is an element of change management here as well, as the industry is certainly not yet ready to do away with the human-in-the-loop.



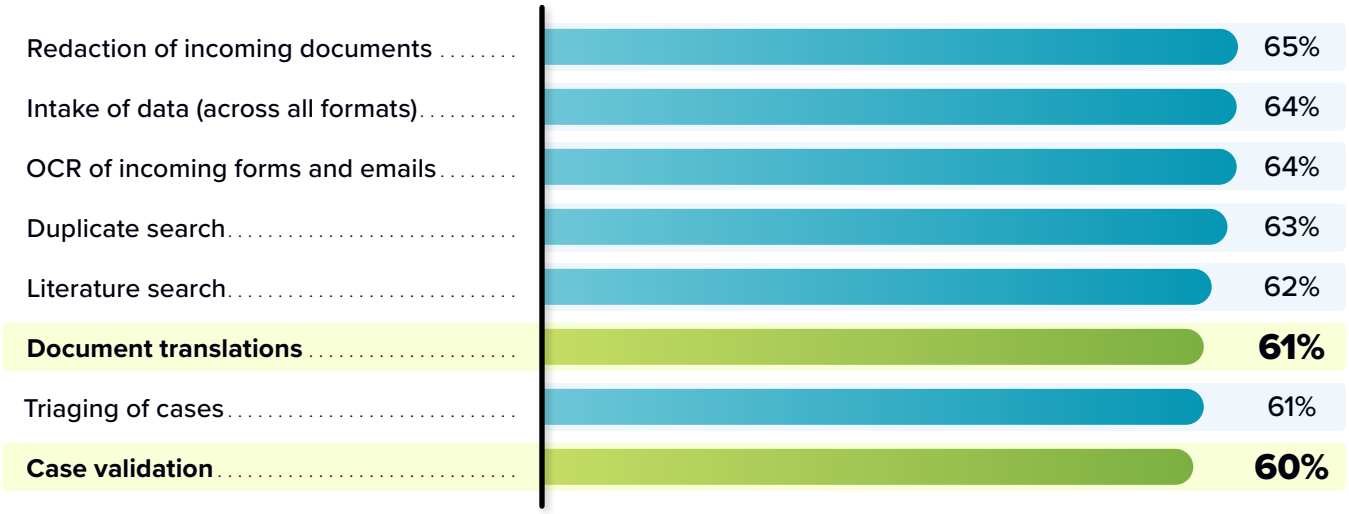
Case Intake — Current and Future

Figure 17 (next page) shows automation of case intake workflows. While case intake continues to maintain high priority, document translations is forecast to move up on the priority list in the next two years. As global markets continue to expand, the need to be able to drive cost efficiencies in the translation process becomes critical. Case validation, which has ranked lowest in maturity in the current process, will become the second highest priority after case intake (see **Figure 18,** next page).

FIGURE 17

Current Automation of Case Intake Workflows

What progress has your organization made in terms of automating the following case intake workflows?
(% of respondents)

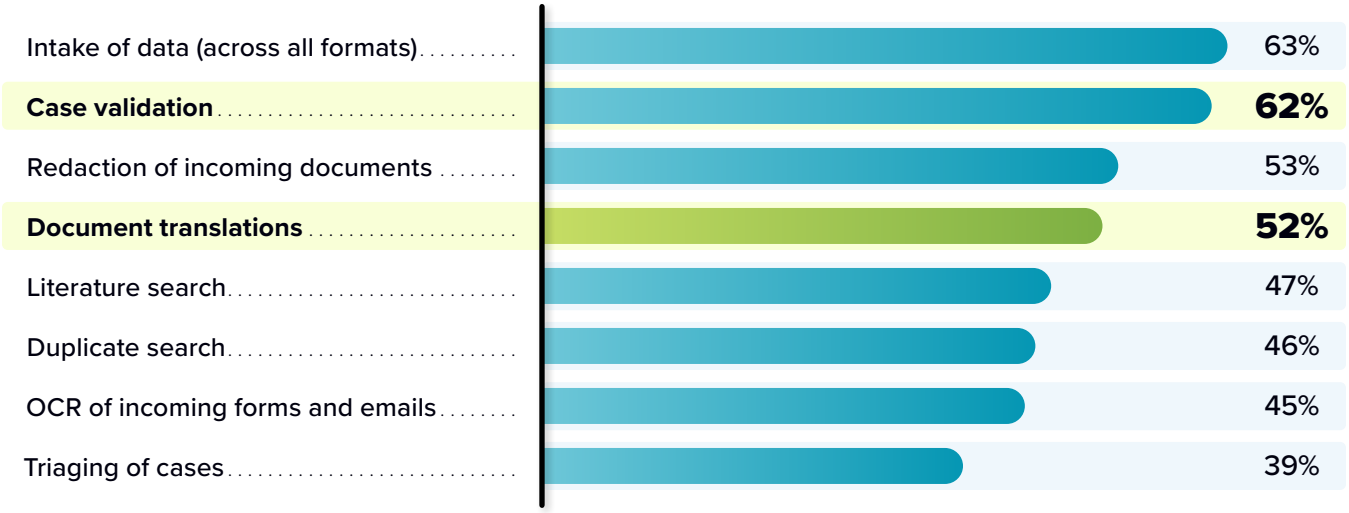


See Appendix for source information.

FIGURE 18

Key Focus Areas for Case Intake Automation Initiatives for PV in the Next Two Years

Over the next two years, which case intake areas will be the focus of new and continuing automation workflow initiatives?
(% of respondents)



See Appendix for source information.

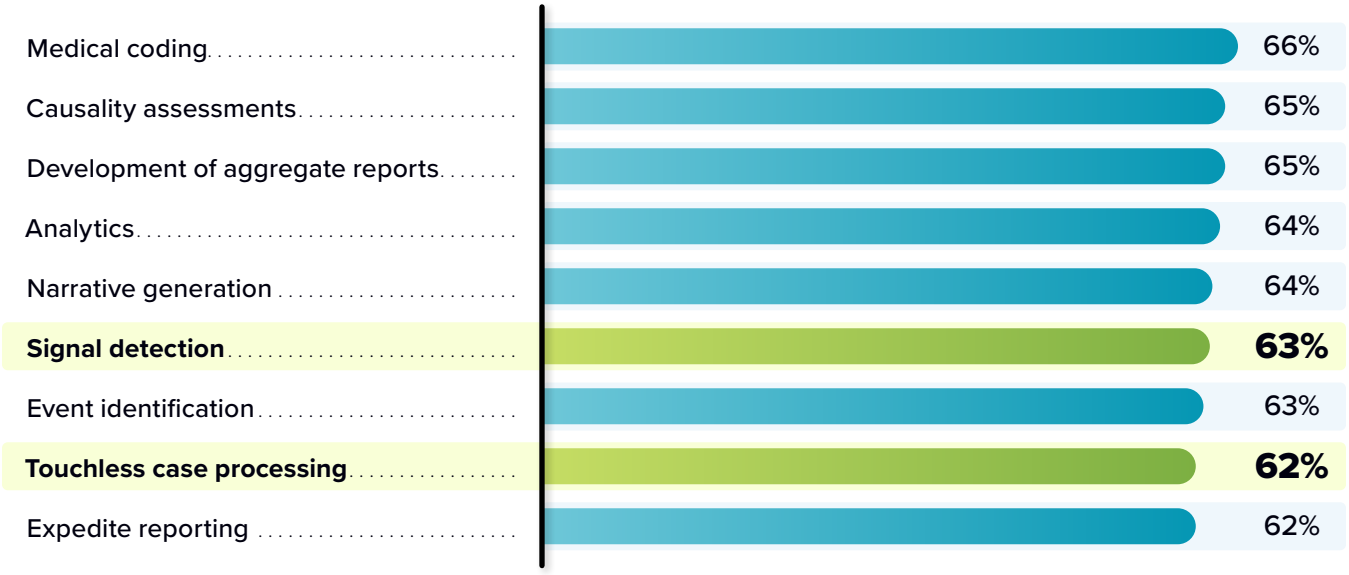
Case Processing — Current and Future

Figure 19 shows automation of case processing workflows. Signal detection, which ranked number six in terms of existing levels of maturity in the automation of PV workflows for case processing, is forecast to move up to number one. Similarly, touchless case processing, which ranked number eight (or second last), is forecast to move up to the second position. This is indicative of a sharp industry focus on outcomes and on efficiencies (see **Figure 20,** next page).

FIGURE 19

Automation of Case Processing Workflows

What progress has your organization made in terms of automating the following case processing workflows?
(% of respondents)



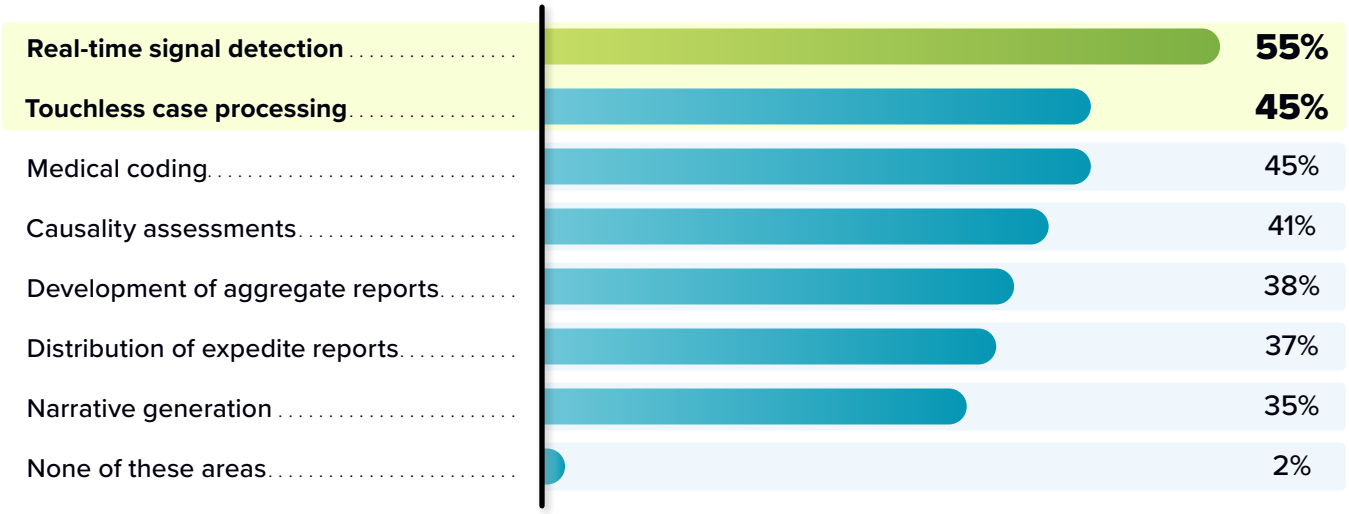
See Appendix for source information.

FIGURE 20

Key Focus Areas for Case Processing Automation Initiatives for PV in the Next Two Years

Over the next two years, which case processing areas will be the focus of new and continuing automation workflow initiatives?

(% of respondents)



See Appendix for source information.

Moving Along the Maturity Curve of PV Automation

One-fourth of the life science industry has identified use cases for PV automation but has not identified implementation partners. Almost two-fifths (39%) of the industry has identified both use cases and partners for the implementation of the same. More than one-tenth (12%)of the industry has its use cases and implementation partners identified and is in a state of data readiness. Only 11% is actually working with its strategic partners to help identify the right use cases for PV automation (see **Figure 21,** next page).

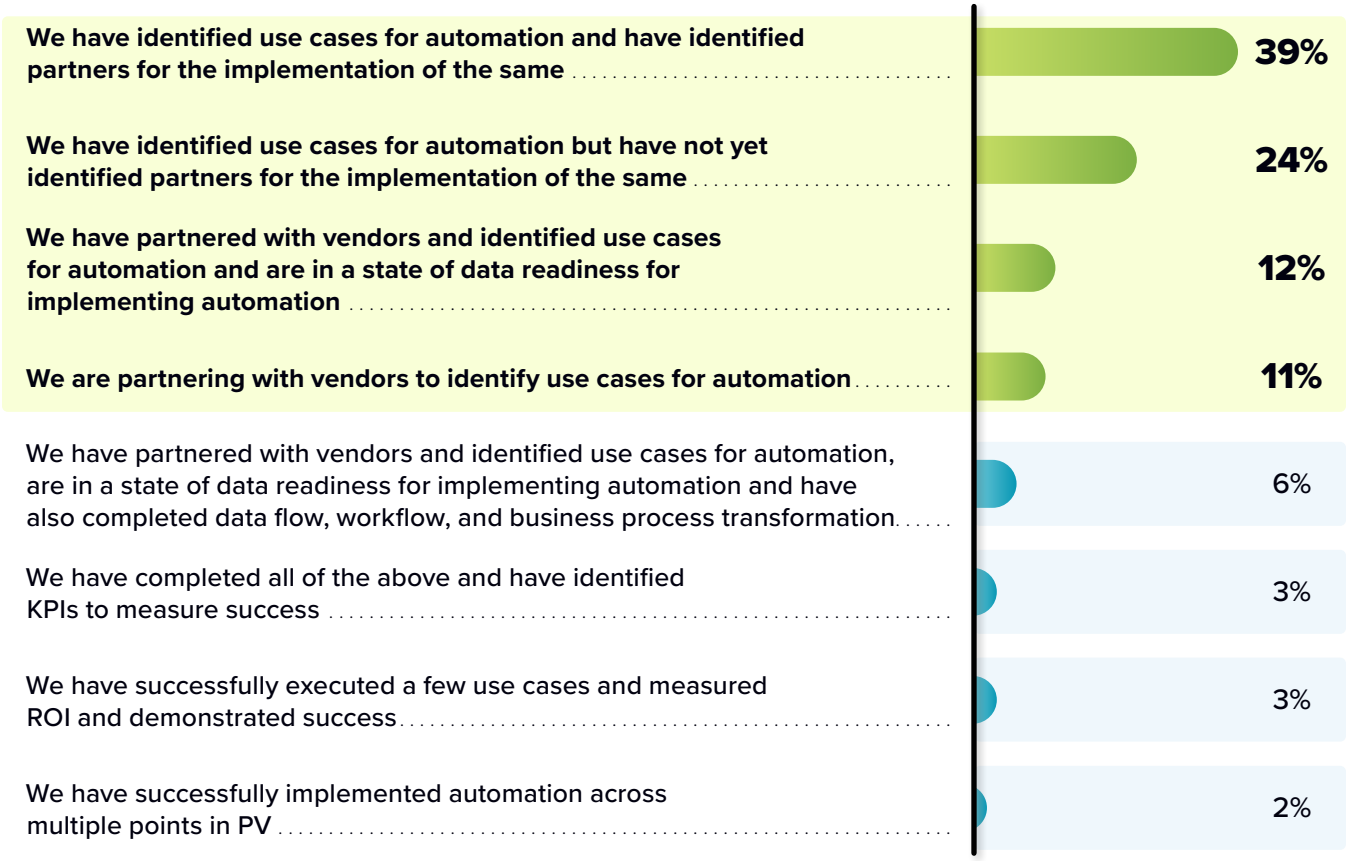
There is wisdom in choosing an experienced partner to choose the right use cases and jointly build the implementation strategy rather than choosing a partner only for implementation purposes. The wrong use cases or an ill-defined road map may have significant impact on the outcomes.

Next levels in the maturity curve include executing data workflows and completing business transformation. The next critical steps include the identification of key performance indicators (KPIs) to measure ROI and then demonstrating success.

FIGURE 21

The Maturity Curve of PV Automation

In terms of the level of adoption of automation in drug safety, which of the following do you currently have in place?
(% of respondents)



See Appendix for source information.

Vendor Selection and Performance Evaluation Criteria

Case Intake

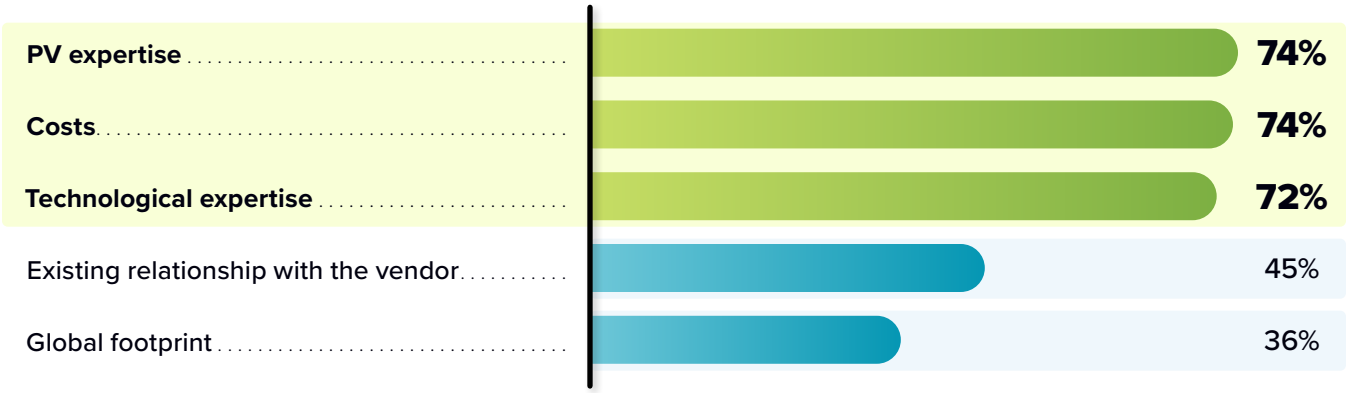
PV expertise ranks the highest (74%), closely followed by costs (74%) and by technological expertise (72%). Thus a deep understanding of the PV domain bears significant value. Almost half of the industry (45%) also gave significant weighting to the existing relationship with the vendor (see **Figure 22**).

FIGURE 22

Vendor Selection Criteria for Case Intake in PV Automation

Which are the key decision criteria for selecting vendors to partner with on PV case intake automation initiatives?

(% of respondents)



See Appendix for source information.

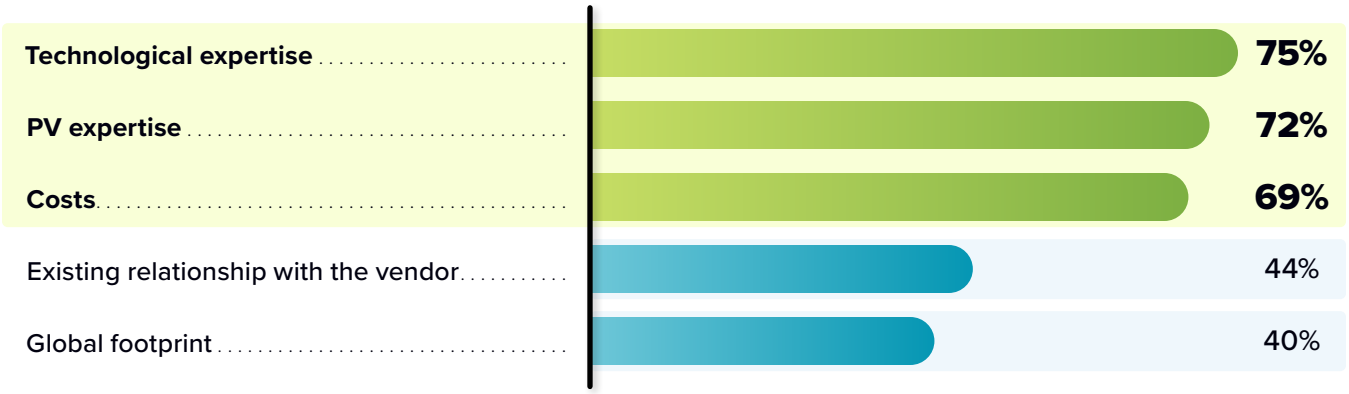
Case Processing

In the case of case processing, technological expertise (75%) took priority over PV (72%), closely followed by costs (69%). Similar weighting was given to the existing relationship with the vendor (44%) (see **Figure 23,** next page).

FIGURE 23

Vendor Selection Criteria for Case Processing in PV Automation

Which are the key decision criteria for selecting vendors to partner with on PV case processing automation initiatives?
(% of respondents)



See Appendix for source information.

Performance Evaluation

More than half of the life science industry considered PV domain expertise a top priority. This was followed by expertise in analytics and insights (39%), expertise in implementation strategy (32%), and maintenance (31%). Other interesting ones that came up were guidance in selecting the right use cases, regulatory compliance, and a global footprint — all very important criteria for building a mature PV implementation strategy (see **Figure 24,** next page).

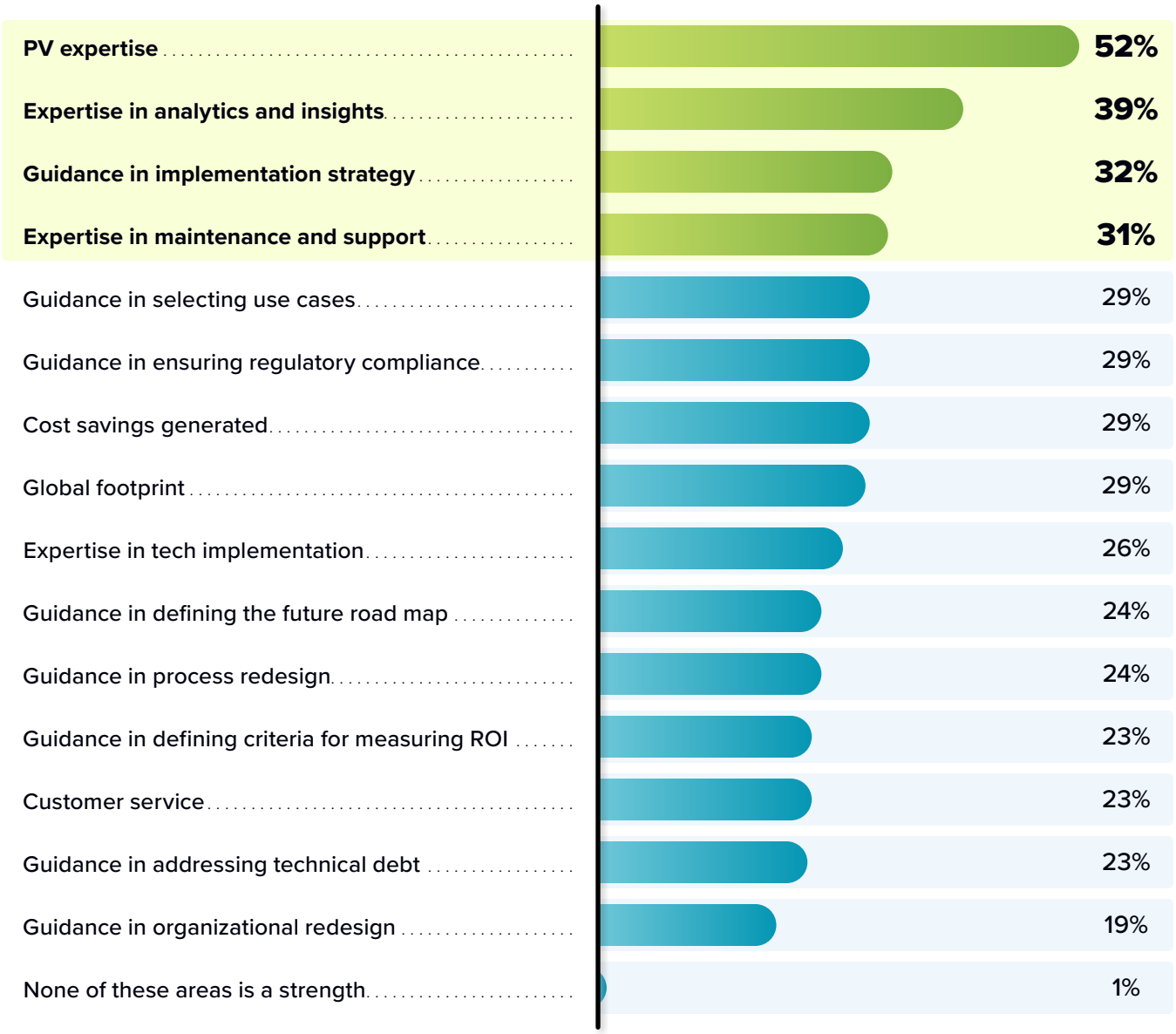
The industry is clearly seeking strategic guidance in building out implementation road maps, as well as process and organizational redesign, and vendors need to step up to this ask.

FIGURE 24

Vendor Performance Evaluation Criteria for PV Automation

What are their most significant strengths taken into consideration when evaluating vendors to support PV automation initiatives?

(% of respondents)



See Appendix for source information.

Future Outlook

The growing number of adverse events, complemented by an increasing pressure to do more with less, is driving the life science industry to rapidly automated PV processes. As organizations move along their PV automation journey, we will see an increasing urgency to adopt next-gen technologies that will help transform existing PV processes. Technology adoption cannot happen on its own and will require change management. Thus, organizations, processes, and technologies will need to evolve in tandem to drive success.

Organization

A mature PV organization is an organization that will have a well-established enterprisewide governance strategy, as well as a culture of innovation, to drive PV automation initiatives. Manual processes will fade away, and there will be an extensive effort to drive automation across the PV value chain. There will be executive commitment to drive multiple PV automation initiatives, and there will be close collaboration between line of business and IT to cull out budgets and prioritize use cases. Organizations will build COEs and upskill teams to leverage newer and more advanced tools and technologies.

Metrics will be delineated and monitored to measure ROI on PV automation initiatives. A certain percentage of cost savings will be ploughed back in to further modernize processes. These organizations will exhibit many of the same characteristics of the level 3 organizations identified in this white paper. The automation of causality assessment and signal detection will be key focus areas. Business outcomes, including driving patient safety while ensuring regulatory compliance, will override operational efficiencies.

Process

As technologies change, workflows will need to evolve in parallel. The COE will design new well-defined standard operating procedures that will ensure that data flows and workflows are aligned. Workflows and data flows will need to be designed with data residency requirements kept in mind, which could otherwise result in critical compliance issues. As M&As continue to increase and restructuring becomes the new norm, resilience and flexibility will need to be embedded in workflows. Process simplification and regulatory compliance will be top of mind.

As organizations transition from level 1 to level 3, PV processes will evolve from tactical and scattered to centralized and consistent, and the automation process itself will throw out alerts in case of non-compliance and generate metrics on measures of success. Subject matter experts with deep domain knowledge will be key to the success of defining and implementing PV processes. Validation will be key.

Technology

While level 1 (emerging) players will focus on the use of manual processes with some level of rule-based automation (such as RPA), level 2 (transforming) players will have moved on to adopt scattered use cases leveraging more advanced technologies such as NLP and machine translation and may have begun dabbling with a few use cases of generative AI. Level 3 (maturing) organizations will have leveraged multiple advanced automation technologies across the PV value chain and will have multiple PV automation workflows nearing completion. These technologies will be able to leverage both structured and unstructured data from diverse sources and transform it to generate real-time insights, powering predictive and preemptive measures to improve patient safety.

Challenges/Opportunities

As organizations seek to improve data intelligence maturity across data cataloging, data governance, and data quality, they will face various challenges that can be turned into opportunities. This can be seen in the survey population and across the maturity scale.

The top 3 most cited challenges facing the life science industry in PV automation are:

- **Regulatory compliance.**
  Significant regional variations in pharmacovigilance regulations have resulted in levels of complexity that are challenging for the industry to deal with. This challenge in itself offers an opportunity, where intelligent automation could make a difference. Whether it is the expedited reporting of serious adverse drug reactions, or ensuring the timeliness and completeness of periodic safety reports, or ensuring the timely notification of health authorities and healthcare professionals regarding the changes to the benefit/risk profile of products, automation has an important role to play. Automation can minimize the risk of human error, improve quality, and drive compliance.

- **Identifying the right use cases.**
  This remains a huge challenge within the organization as a result of a lack of knowledge of where the maximum ROI lies. An experienced partner can play a critical role in helping strategize and architect the road map for use case implementation. Identifying a partner of choice for driving PV automation initiatives remains a challenge to 30% of the life science industry today as per the IDC survey. Partners can help prioritize use cases but, in addition, can also identify the right technologies for specific use cases. Thus, for case intake and for the triaging of cases, RPA may be the technology of choice, whereas for signal detection or for causality assessment, generative AI may serve as a far more powerful tool. Therefore, choosing the right technology for the right use case may result in faster implementation and higher cost savings.

- **Lack of well-established governance models for AI implementation.**
  One-third of the life science industry cited this as a key concern, clearly establishing its importance. While 42% of the industry reported that it had an enterprisewide governance strategy in place, a lot more needs to be done. There is a recognition of the importance of implementing PV automation initiatives, resulting in the sprouting of pockets of PV automation initiatives, and a lack of governance could result in a lot of technical debt and futile

efforts without meaningful outcomes. This is where level 3 organizations will differentiate themselves, working across carefully architected governance models.

The key opportunities that lie in PV automation are well assessed by deliberating upon the improvement in business outcomes seen when implementing PV automation initiatives. An improvement in patient safety, generating real-time insights, improved compliance, and fewer product recalls, translates into improved credibility and standing in the industry, and this is the industry's ask; this is where the true payoff from PV automation initiatives will lie. Level 3 organizations will prioritize these business outcomes over operational efficiencies.

Conclusion

While almost every process in PV can be automated, and the industry is certainly headed in that direction, it is still not there. Exponential increases in case volumes, more stringent and complex globally regulatory requirements, and an increasing need to drive cost efficiencies are all driving the use of automation in PV. Level 3 (maturing) organizations will lead the way, adopting advanced technologies, putting the right governance model in place, and executing a well-thought-out implementation strategy to drive success. Top management support will be key. Organizations will need to upskill and to manage change. The human-in-the-loop will need to be an integral part of all the PV automation initiatives and will help build trust.

Appendix

Data Source (for all figures)

n = 208
Base = all respondents
Notes: Data is managed by IDC's Global Primary Research Group. Data is not weighted.
Multiple responses were allowed. Use caution when interpreting small sample sizes.
Source: IDC's *IQVIA Automating Drug Safety Surveillance Survey,* October 2023

Demographics of Survey Respondents (Figures 25–31)

FIGURE 25

Country

In which country do you primarily work?
(% of respondents)

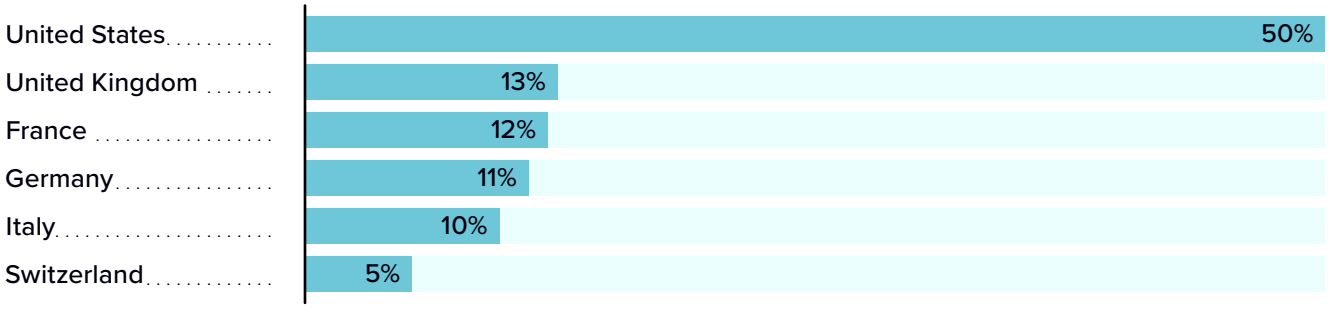


FIGURE 26

Global Company Size

What is your best estimate of the number of employees in your organization worldwide?
(% of respondents)

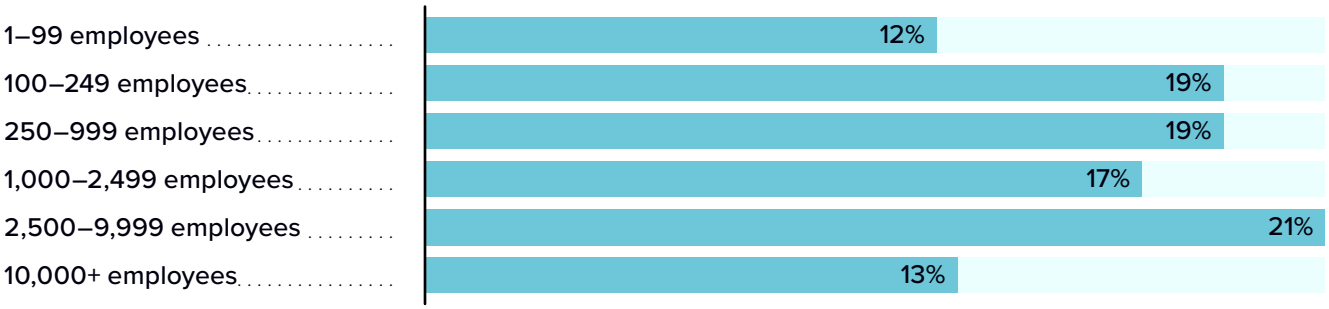


FIGURE 27

Global Company Revenue

What is your organization's revenue (in U.S. dollars, euros, or U.K. pounds equivalents)?

(% of respondents)

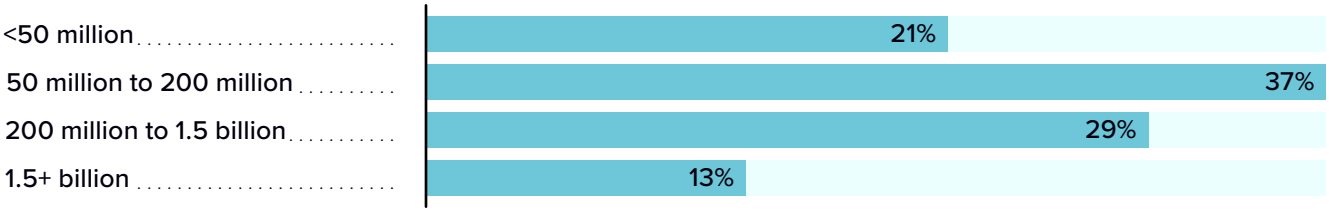


FIGURE 28

Role-Based Demographics — Decision-Maker or Influencer

Are you a decision-maker or an influencer?

(% of respondents)

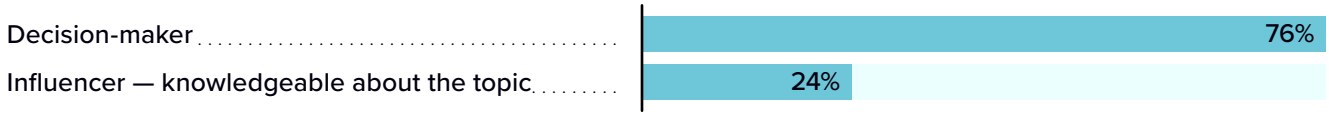


FIGURE 29

Role-Based Demographics — Position

What is your position in your organization?

(% of respondents)

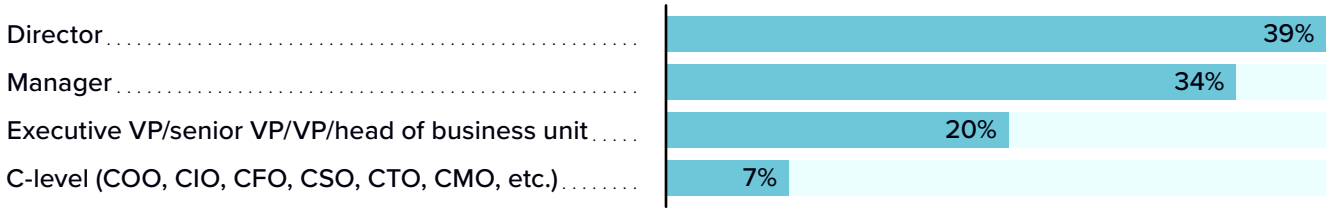


FIGURE 30

Role-Based Demographics — Job Role

What is your job role?

(% of respondents)

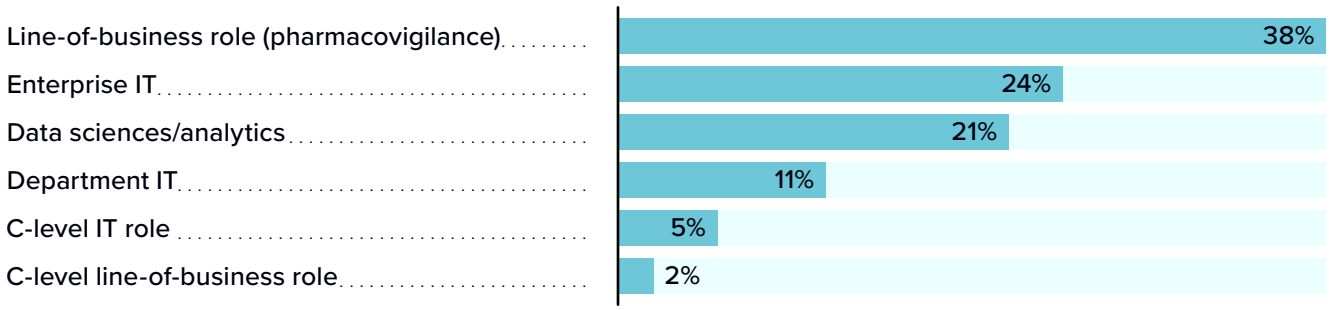
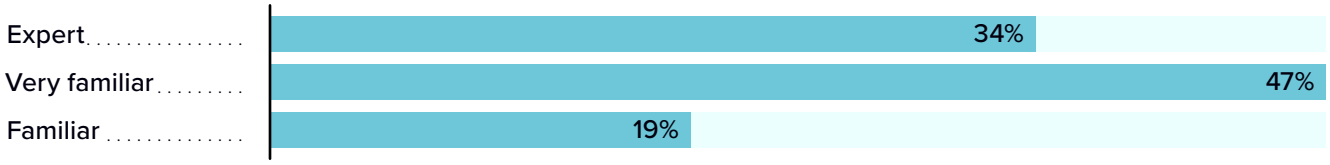


FIGURE 31

Domain Expertise

What is your level of familiarity with pharmacovigilance?

(% of respondents)



Building the Maturity Scale

In building the safety automation maturity scale, the goal is to score respondents from 0 to 100, with inputs derived from attributes that measure their maturity or approach to drug safety surveillance.

Three attributes were selected to measure maturity in drug safety surveillance in the survey instrument:

- **Attribute 1:** Count of case intake workflows nearing completion or complete
- **Section B:** Count of case processing workflows nearing completion or complete
- **Section C:** Current approach to using generative AI to drive automation in PV

The IDC approach was to build an overall score by combining the scores on the three questions, with each input weighted equally and adjusted to be on a 0–100 scale.

The overall score demonstrated good correlation to the business outcome and PV metrics scores.

The business outcome scores were based on the three most important business outcomes that the organization was trying to achieve from investments in implementing automation in PV in the past 12 months (measured across eight criteria) and the annual percentage change achieved over 12 months.

The PV metrics scores were based on the most important metrics that the organization used to assess performance related to investments in implementing automation in PV over 12 months (measured across eight criteria) and the annual percentage change achieved over 12 months.

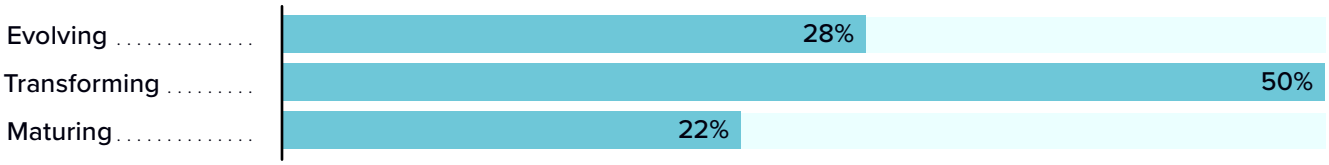
The overall scale is calculated to be the average score across all the subscales (equal weighting).

To aid in analysis, IDC created three subgroups for the initial analysis based on percentiles, as illustrated in **Figure 32.**

FIGURE 32

Distribution of Safety Automation Maturity Levels — Final Maturity Segments

(% of respondents)



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Dr. Nimita Limaye is a Research VP with IDC Health Insights and provides research-based advisory and consulting services as well as market analysis on key topics related to R&D Strategy and Technology in the life science industry. She addresses aspects such as the role of digital transformation in discovery research, pharmacovigilance, decentralized clinical trials, risk-based monitoring, as well as the role of NLP, AI, ML, DL, and RPA, in transforming drug development, precision medicine, pharma R&D execution, and evolving strategic outsourcing and pricing models. Nimita represents healthcare and life sciences on IDC's AI Council. She is also the past chair of the board of the Society of Clinical Data Management.

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