



Original Research

Effects of the COVID-19 Pandemic on Pharmacovigilance Strategy, Systems, and Processes of Large, Medium, and Small Companies: An Industry Survey

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ABSTRACT

Purpose: The COVID-19 pandemic poses an unprecedented threat to global business relationships and dynamics. The pharmacovigilance function of pharmaceutical companies is particularly susceptible to changing external pressures because of its highly structured compliance activities. We conducted an industry-wide survey to provide insights on how the pharmacovigilance function responded to the challenges posed by the pandemic. We compared smaller companies and larger companies regarding impact on portfolios and operational activity metrics.

Methods: We conducted a survey through the Navitas Life Science annual benchmark of pvnet[™], a network of large enterprise (LE) companies, and pvconnect[™], a network of small and medium enterprise (SME) companies, using an online surveying tool during the first quarter of 2021. We collected information on pharmacovigilance activities, including quantitative measures of workload, costs, and key performance indicators, and qualitative data on the effects of the pandemic on product portfolios and operations.

Findings: Survey questions were posed to LE (pvnet) network members (n = 12) and SME (pvconnect) network members (n = 18) for the period from January 1 through December 31, 2020. The date of data collection was March 26, 2021. Descriptive median values of parameter metrics included the following: revenue (\$28.4 billion for LE companies and \$1.6 billion for SME companies), number of products (127

for LE companies and 19 for SME companies), and volume of individual case safety reports (391,000 for LE companies and 13,000 for SME companies). SME companies reported a greater impact on 2 survey categories, remote working and employee well-being, than did LE companies. However, LE companies reported a greater impact than did SME companies on all other survey categories: effect on strategic priorities, shift in product focus, workload changes, changes in sourcing model, effect on case reporting compliance, effect on business continuity, changes in pharmacovigilance technology strategy, impact of interactions with health authorities, effect on resource capacity, and impact on recruitment.

Implications: Four major themes emerge from this survey: (1) shift to remote working, (2) recognition of the impact on employee well-being, (3) shift in strategic priorities, and (4) newly recognized aspects of risk mitigation. The COVID-19 pandemic has had a marked effect on every aspect of pharmaceutical companies' pharmacovigilance functions, although the effects appear to be different for LE companies than for SME companies. (*Clin Ther.* 2022;44:1225–1236.) © 2022 The Author(s). Published by Elsevier Inc. This is an open access article under the CC BY-NC-

Accepted for publication July 16, 2022

<https://doi.org/10.1016/j.clinthera.2022.07.007>

0149-2918/\$ - see front matter

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Keywords: business continuity, business operations, COVID-19, pharmaceutical industry survey, pharmacovigilance, workforce.

INTRODUCTION

The COVID-19 pandemic brought to the world an abrupt awareness of the profound, unprecedented threat posed by the coronavirus and its evolving genome to individual health, organizational structures, and global business relationships and dynamics. Business continuity has become the catch phrase, and robustness and resilience are the sought-after goals,¹ but appreciation of the pandemic's effects on processes at the granular level has been slower in coming.

The discipline of business continuity has evolved significantly since the 1970s, when the basic model primarily reflected a reactive approach to crisis management when faced with unexpected problems that arose. For example, in the United States in 2006, the White House Security Council prepared a National Strategy for Pandemic Influenza² without business continuity as an explicit topic. In counterpoint, Ireland's Department of Enterprise, Trade, and Employment explicitly addressed the issue of business continuity in 2007 by conducting 12 case studies for a hypothetical influenza pandemic in varied business sectors, including food processing, financial services, engineering, and medical devices.³ Today, business continuity management is a discipline of its own, and the World Health Organization is in its third iteration of global health recommendations for business continuity planning to address a potential influenza pandemic.⁴

Business continuity planning has become an essential function of the pharmaceutical industry. Maintaining business activities with the least degree of disruption in the face of disaster requires safeguards for business staff, and development of other measures that can ensure availability of essential drug products and compliance with regulatory requirements, including inspections.⁵ With specific regard to pharmacovigilance (PV), the European Medicines Agency identified critical PV processes from a business continuity perspective as early as 2012 in its Good Pharmacovigilance Practices⁶ and published detailed guidance following the COVID-19 pandemic in 2020.⁷ Likewise, the US Food and Drug

Administration has a guidance document in place, *Planning for the Effects of High Absenteeism to Ensure Availability of Medically Necessary Drug Products*, to support the nondisruption of critical processes.⁸ Similarly, developing countries have created training activities to identify critical PV processes to establish business continuity procedures,⁹ consistent with the European Medicines Agency's Good Vigilance Practices.

In general, PV is presently understood as the science and activities related to the detection, assessment, understanding, prevention, and communication of adverse effects or any other medicine-related problem to the appropriate stakeholders.¹⁰ Broadly speaking, the PV system includes the following major categories of functions¹¹: (1) case management (event collection, case processing, individual case safety report [ICSR] and suspected unexpected serious adverse reaction reporting to regulatory authorities, and aggregate case evaluation and reporting to regulatory authorities); (2) signal management (signal surveillance, detection, evaluation, governance, communication, and documentation); and (3) benefit-risk management. Today's PV systems rely on sophisticated, proprietary databases to operationalize these functions, track activities at evidentiary level of standards, maintain security against global hackers, and ensure compliance with health care standards of confidentiality of the information in the company's control. Examples of current vendors in this space include Argus,¹² ArisG,¹³ and IQVIA¹⁴

We conducted an industry-wide convenience sample survey to provide descriptive insights into the impact of the COVID-19 pandemic on the PV function in smaller and larger biopharmaceutical companies regarding how these companies responded to the challenges of a changing landscape of pandemic dynamics on PV infrastructure and practices. We present comparisons between smaller companies and larger companies regarding the impact on product portfolios and on PV operational activity metrics.

METHODS

Cross-Industry, Self-selected Networks of PV Leaders

Navitas Life Sciences, a subsidiary of TAKE Solutions, is a life sciences-focused consulting, technology, and services company. As part of its activities, Navitas Life Sciences collects workload indicators on an annual basis from these organizations to establish network benchmarks for its members.¹⁵ pvnet is

a network specific for PV professionals from large biopharmaceutical organizations, defined as typically having a mean annual revenue of \geq \$10 billion or greater. As of October 2021, the network consists of 17 self-selected, large global biopharmaceutical organizations that have been operational since 2001. Members of pvnet are typically global heads of PV departments and their leadership teams who are responsible for deploying the PV strategy within their organizations. pvconnect is a network specific for PV professionals from small and medium biopharmaceutical organizations, defined as typically having a mean annual revenue of $<$ \$10 billion. As of October 2021, the network consists of 35 self-selected, small and medium global biopharmaceutical organizations that have been operational since 2005. Members of pvconnect are typically heads of PV departments and their functional leaders who are responsible for deploying the PV strategy within their organizations.

Survey of PV Operations

The annual PV benchmark is a survey exercise run during the first quarter of each calendar year since 2002, with the objective of gathering a broad set of comparable industry data focused on PV. Each survey is designed and drafted as informed by regular consultation and feedback from key, volunteer industry PV experts who are members of the pvnet and pvconnect networks.

We focused on the impact that COVID-19 has had on PV strategy, systems, and processes in the context of baseline and demographic data. The primary goals are to compare quantitative information, such as PV workload, costs, and key performance indicators, among peers and to allow each member company to see its own data in the context of their anonymized, aggregated peers and the wider industry. In addition, more qualitative data are collected to provide spotlights on global events and hot topics or to take regular snapshots of common PV operational practices to highlight change over time. The 2021 PV benchmark included several questions to determine the impact of the COVID-19 global pandemic on PV product portfolio, workload, finances, and operations.

Survey topics were gathered from PV experts in industry from across the size spectrum of small to medium and large pharmaceutical companies. A draft questionnaire was prepared by Navitas PV subject matter experts using data-driven survey

methods. Questions focused on the following specific areas: remote working, employee well-being, strategic priorities, product focus shift, workload changes, ICSR compliance changes, business continuity, PV technology strategy, health authority interactions and inspections, resource capacity, and recruitment. The draft was reviewed and approved by a panel of industry experts in PV. This process lasted 6 months. The survey was launched in early February 2021, and responses were collected after 6 weeks, on March 26, 2021.

Anonymity was maintained by unmasking the source of individual company responses only to each individual company that participated in the survey. Aggregate data are given only when they were taken from a minimum of 5 companies. No raw data are shared outside the Navitas network's department.

After the data collection was closed, Navitas' business intelligence analyst performed the data cleaning, aggregation, modeling, and visualization and worked with Navitas' subject matter experts to interpret key findings. All descriptive analysis and visualization work was performed using Microsoft Excel (Microsoft Inc, Redmond, Washington). Statistical work was restricted to descriptive analyses.

Line distances were calculated using the formula $[(x_1 - x_2)^2 + (y_1 - y_2)^2]^{0.5}$. This calculation is of an arbitrary dimension intended to give only the relative differences between pvnet and pvconnect for a given survey topic.

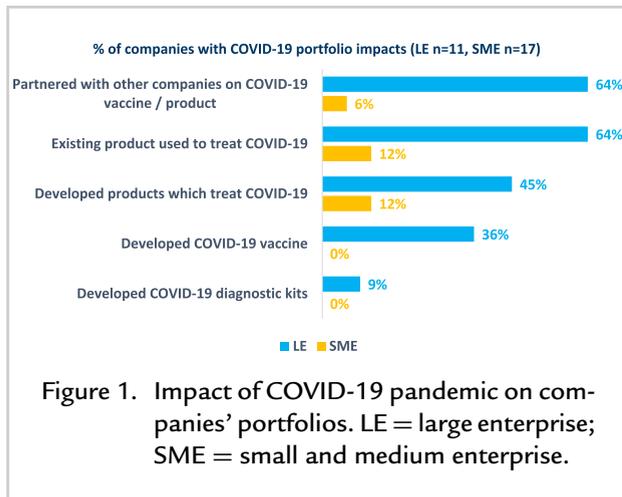
RESULTS

Description of Data Set

Survey questions were posed to large enterprise (LE) (pvnet) members ($n = 12$) and small and medium enterprise (SME) (pvconnect) members ($n=18$). The period of interest is January 1 through December 31, 2020. The date of data collection was March 26, 2021. Descriptive median values of parameter metrics for LE and SME companies include the following: revenue (\$28.4 billion for LE companies and \$1.6 billion for SME companies), number of products (127 for LE companies and 19 for SME companies), and volume of ICSRs (391,000 for LE companies and 13,000 for SME companies).

Description of Impact of COVID-19 Pandemic on Companies' Portfolios

The way in which LE and SME companies' portfolios were affected by the COVID-19 pandemic



is shown in Figure 1. Overall, for LE companies, 9 of 11 (82%) reported that their portfolios were directly affected by COVID-19, whereas for SME companies, 4 of 17 (24%) reported that their portfolios were directly affected by COVID-19. Specifically, for LE companies, 7 of 11 (64%) reported partnering with other companies to develop a vaccine or other product, 4 of 11 (36%) reported developing a vaccine, and only 1 of 11 (9%) reported developing a diagnostic test kit. For SME companies, only 1 of 17 (6%) reported partnering with other companies to develop a vaccine or other product, none of 17 (0%) reported developing a vaccine, and none of 17 (0%) reported developing a diagnostic test kit.

Description of Impact of COVID-19 Pandemic on Companies' Strategies, Systems, and Processes

Figure 2 shows the relative distance between pairs of company networks, LE and SME companies, for a given category of topic items, in decreasing order of difference, that identifies the extent to which the 2 networks have differing perspectives regarding the influence of COVID-19 on the survey item. Bars for 2 categories (remote working and employee well-being) reflect a substantially greater effect on SME companies (those going to the left of center), and the remaining 10 categories reflect greater effect on LE companies (those going to the right of center).

Individual comments are summarized here. Two categories (remote working and employee well-being) that reported stronger effects on SME network companies than on LE network companies are discussed first,

reflecting comments made in the survey. For all other topic categories, LE companies are discussed first.

Remote Working

SME companies reported greater flexibility in remote working capacity than did LE companies. They also reported greater recognition of the importance of implementing digital tools to facilitate remote communication, and they identified the potential negative impact on physical health and well-being due to long-term suboptimal working conditions. They further identified the importance of greater work schedule flexibility and work-from-home options and the need for ergonomic measures to mitigate family and workplace stressors.

LE companies reported an expectation that virtual interactions will become the eventual norm, with a still uncertain degree of return to onsite working in the future. Working proficiency is expected to improve as virtual collaboration tools are refined and integrated into the workstream. LE companies reported that remote working capability may change the overall approach to work into the future.

Employee Well-being

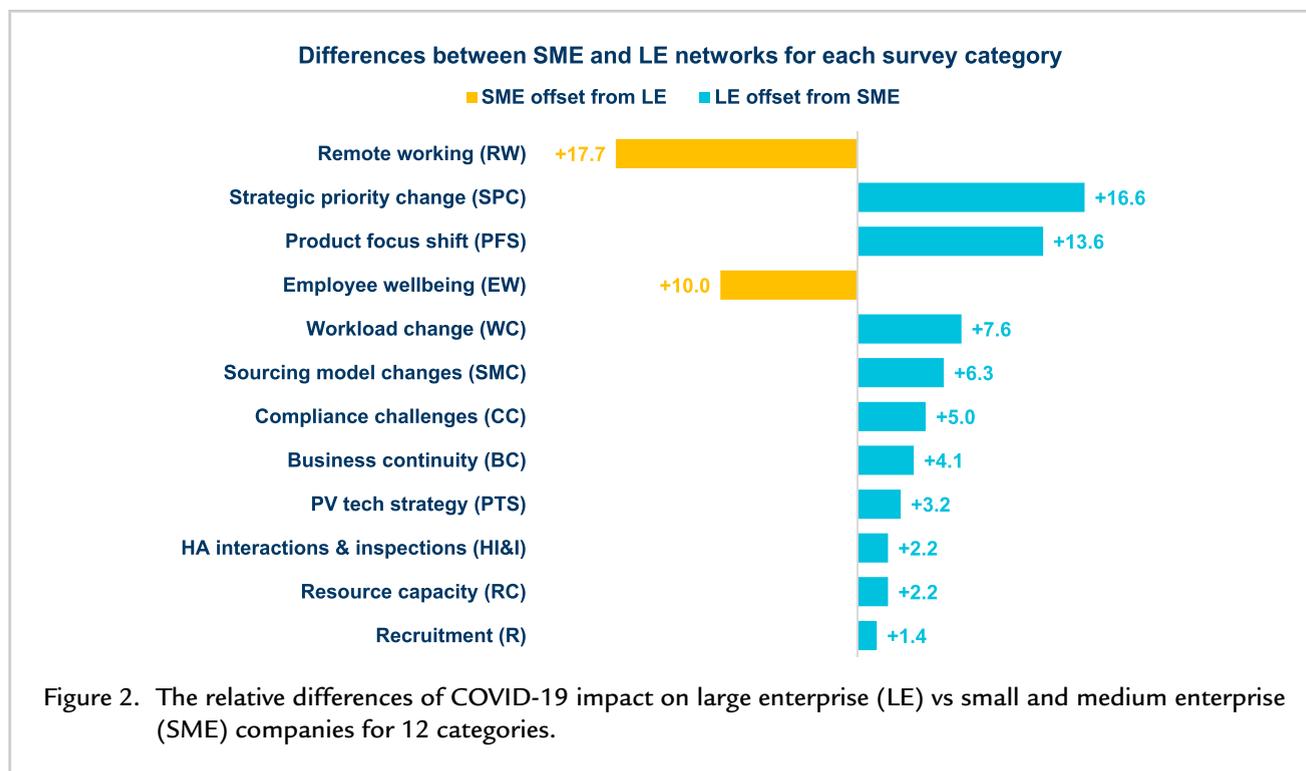
SME companies reported concerns about issues of mental health and well-being, noting loneliness and absence of in-person interactions.

LE companies reported that lockdowns had a negative effect: isolation and prolonged remote work led to loss of camaraderie, whereas regular contacts lessened the effects by helping to maintain sense of belonging. LE companies reported that resources were made available to mitigate effects of stress. In response, there was a greater degree of global communication. A survey that was conducted in one company's vaccine unit reported greater well-being.

Strategic Priorities

LE companies reported that continued emphasis on vaccines and treatments for COVID-19 would require long-term changes: resource reallocation, organizational restructuring, and accelerating processes for automating case management.

SME companies reported that they evaluated plans and timelines more cautiously and weighed priorities more carefully. They became more determined to recognize individual and group efforts.



Product Focus Shift

LE companies reported an emphasis of near-term and midterm focus on COVID vaccine, although they expect to return to their former profile of products and activities in the long term. They investigated whether established drugs could be repurposed to treat COVID-19 disease.

SME companies reported an increased focus on product development, including safety science strategy.

Workload Changes

LE companies reported an expected significant increase in case volume in 2021 because of introduction of vaccines and therapies (including off-label use) to treat COVID-19. This increase is expected to drive the already accelerating trend to greater automation and improved workflows. There is also a substantial shift in the location where work is being conducted, from in office to at home, which further required reallocation of resources and organizational restructuring.

SME companies reported mixed effects on case volume, associated with mixed effects on contractor support to review cases.

Sourcing Model Changes

LE companies reported that the new, unplanned COVID-19 vaccine and repurposed drugs for treatment of patients with COVID-19 infection have led to temporary outsourcing of activities for uncertain duration and consequently the need to qualify more vendors.

SME companies reported no details.

ICSR Compliance Changes

LE companies reported that early in the pandemic there was a stronger effect on case volume related to patient use of repurposed drugs, and a higher priority was placed on accelerating automation to deal with greater volumes.

SME companies reported that the unpredictability of case volume led to efforts to improve methods of adaptation.

Business Continuity

LE companies reported an expectation of permanent workforce shift to remote work to meet compliance requirements and thus ensure business continuity, which,

in turn, required development of new approaches to ensure backup capacity.

SME companies reported the need for more thorough global alignment. In the long term, their focus must broaden beyond case processing to include critical processes and deliverables, which will be reflected in a greater degree of permanent remote work.

PV Technology Strategy

LE companies reported that COVID-19 has challenged management to adopt automation more quickly and to look for more opportunities to automate routine activities. Insights extend to related areas, such as length of validation processes and number of vendors. Ultimately, this encourages more agile processes and decision-making. There is now consideration of intelligent automation to enhance efficiencies.

SME companies reported consideration of ways to reduce manual processes for employees working remotely. One company was able to implement a robotics program while working remotely.

Health Authority Interactions and Inspections

LE companies reported that remote formats were introduced to inspection management processes. Multiple challenges resulted, including technology failures, unavailability of staff in designated time zones, poor backroom coordination, and unanticipated increase in document review by inspectors. Companies had to leverage different geographic hubs to support remote inspections to accommodate global locations of sites. LE companies reported uncertainty about how these experiences may affect frequency of inspections. However, at least 1 health authority (Medicines and Healthcare Products Regulatory Agency) continues to expect companies to host on-site inspections.

SME companies reported comfort with remote work. Organizational redesign resulted in more clearly defined roles and responsibilities. There is the recognition that a shift to more frequent remote inspections will require a higher degree of coordination and teamwork to secure favorable outcome.

Resource Capacity

LE companies reported that having a new, unplanned COVID-19 vaccine required continued review of resource demands and processes to meet a highly dynamic environment.

SME companies reported that outsourcing led to the recognition that there may be even more opportunities to outsource, thus leading to changes in the way that work is done.

Recruitment

LE companies reported recognizing that because successful candidates do not necessarily need to relocate, the talent pool has become markedly larger, relieving a strain in recruitment. In turn, they bring stronger remote-working skills, stronger virtual team skills, and more cohesive cultural experiences.

SME companies reported recognizing the opportunity to have greater flexibility through remote recruitment.

Impact of COVID-19 Pandemic on PV Operations

For all LE network companies, whether or not their portfolios were affected by COVID-19, PV operations were affected for all affiliates and for all ICSR processing. For LE companies with portfolios that were both affected and unaffected by COVID-19, operations were affected to varying degrees: for aggregate reporting (56% for affected companies and 67% for unaffected companies), signal management (78% for affected companies and 67% for unaffected companies), and risk management (78% for affected companies and 33% for unaffected companies).

For SME companies with portfolios that were both affected and unaffected by COVID-19, PV operations were also affected to varying degrees: for affiliates (100% for affected companies and 27% for unaffected companies), ICSR processing (100% for affected companies and 57% for unaffected companies), aggregate reporting (25% for affected companies and 14% for unaffected companies), signal management (0% for affected companies and 31% for unaffected companies), and risk management (0% for affected companies and 29% for unaffected companies).

Figure 3 shows the top 3 PV operational activities in each of the 4 major areas (ICSRs, aggregate review, signal management, and risk management) for which COVID-19 had a greater degree of impact for LE companies than for SME companies.

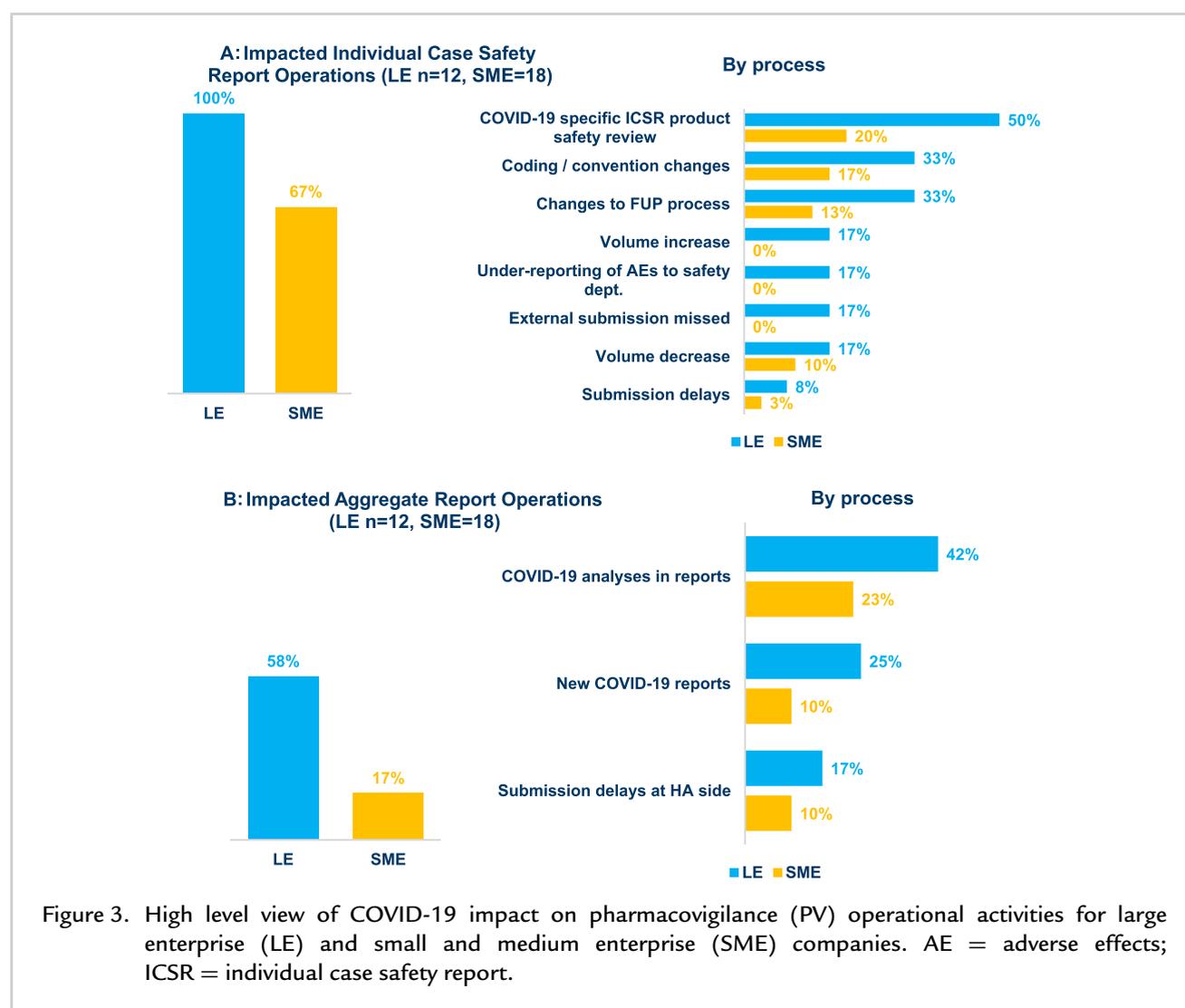
DISCUSSION

The COVID-19 pandemic took the world by surprise and had consequentially devastating effects on human life and well-being¹⁶ and on the world's

economies¹⁷ and cultures.¹⁸ In response, the development, regulatory authorization, and distribution of targeted vaccines have also been extraordinarily unprecedented in effect. We have learned to develop new vaccines with never-before-used technologies, in substantially shortened fractions of the historically experienced timeframes, at orders of magnitude larger volumes, and with ranges of protection and safety profiles consistent with older and more experienced vaccines.¹⁹ Although global distribution remains a distressing, if not intractable, political problem,²⁰ the pandemic in much of the developed world has primarily become a pandemic of those who are hesitant about being vaccinated and of those who are unvaccinated.²¹ PV is an important component

in the campaign that continues to chip away at the resistance.^{22,23}

PV itself has evolved significantly during the past 2 to 3 decades.¹¹ Activities that were once primarily ad hoc and variable in application from company to company are now standardized, processes that were once restricted to individual reports are now also routinely conducted on aggregated reports, procedures that were once limited to descriptive methods are now routinely expanded to include quantitative approaches, and statutes reflective of high-level policy perspectives that were once fundamentally reactive in approaching solutions to system-wide problems are now increasingly being approached in a proactive manner. For example, there is the US



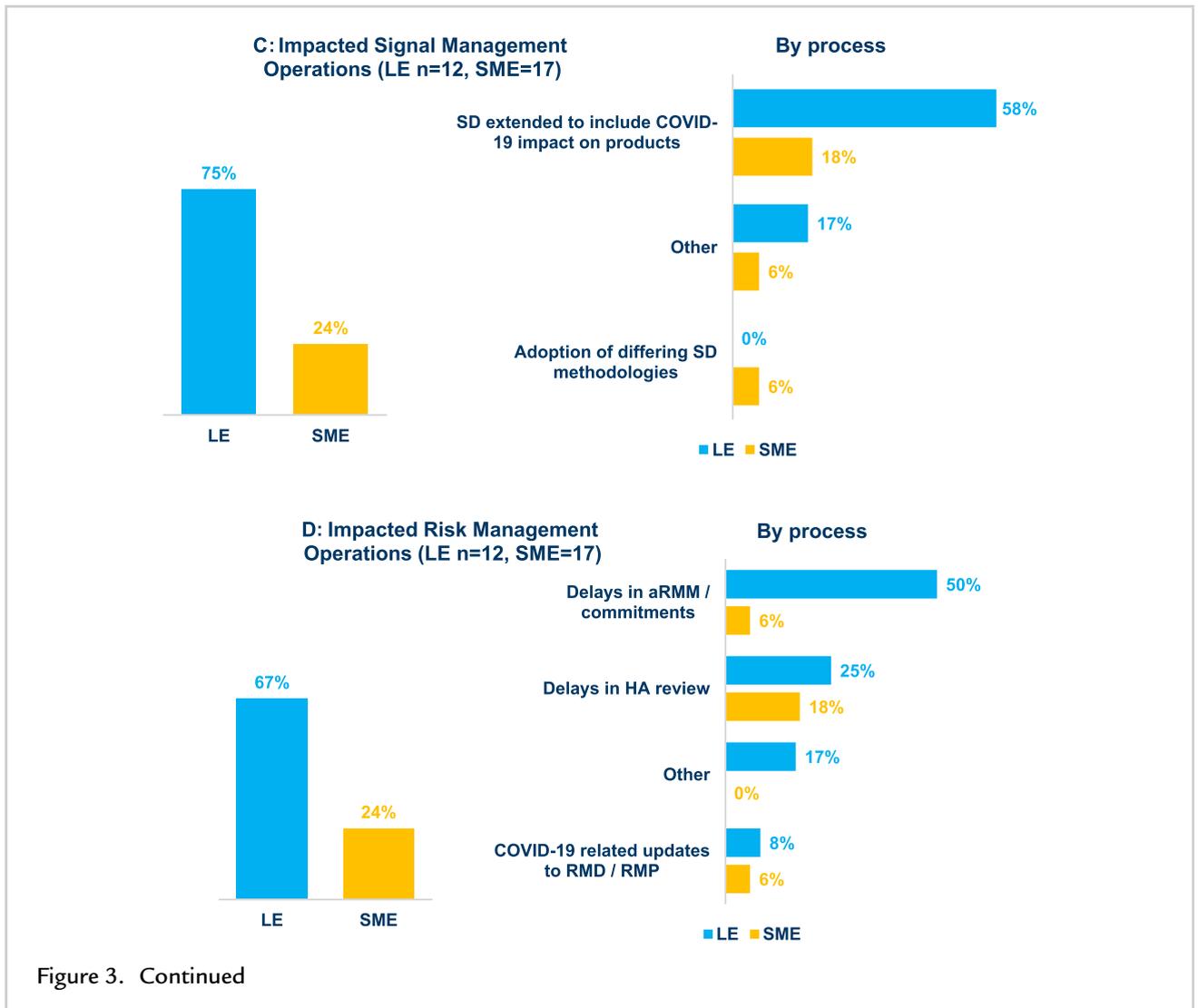


Figure 3. Continued

Food and Drug Administration’s Sentinel Initiative, an active surveillance system that has access to the medical records of >200 million patients in the United States through collaboration with 17 health care partners that can conduct prospective and retrospective epidemiologic analyses in a matter of months rather than the 1 to 3 years it would have taken before the availability of Sentinel.²⁴

During these last several decades, PV has, at the organizational level, undergone a major evolution to form the 3 distinct sets of functions described in the Introduction: case management, signal management, and benefit-risk management.¹¹ Following the September 11, 2001, attacks in the United States, multiple regulatory changes were legislated in the United States,

as well as in many other countries, in the decade that followed to enhance response capabilities, known as medical countermeasures, to threats related to chemical, biological, radiological, or nuclear agents.²⁵

However, none of these transformational changes anticipated or were sufficient to address the breadth of the impact of the COVID-19 pandemic.²⁶ The shortfalls have highlighted the critical importance of a rigorous business continuity planning process. The reporting component of PV activities is a particularly informative example because of the necessary hands-on tasks that took place on site during the first year of the pandemic before the availability of COVID-19 vaccines. Business practices have varied in different parts of the world, in part because of the need

for relatively stringent, protective, social distancing practices in the community, whereas there have often been significant regional differences on the use of public transportation with accompanying differences in the risk of exposure to COVID-19. There have also been regional failures to provide adequate control of the pandemic, and the scenarios for recovery have varied widely over geographic regions.²⁷ This backdrop provides the context for interpreting and understanding the results of this industry survey.

At the most general level, all member companies were clearly unprepared for business disruption of this magnitude. Although this was a self-selected sample of companies, the pervasive sweep of reported effects across all member companies can reasonably be generalized across the industry for the corporate PV function and likely, though to an uncertain degree, across other pharmaceutical corporate functions. Given that the last pandemic was a century earlier, no business could have been expected to be prepared; all routine business continuity plans have limitations in budget, experience, and readiness. Still, several themes are seen to emerge as the most substantive findings from this survey: (1) shift to remote working, (2) recognition of the impact on employee well-being, (3) shift in strategic priorities, and (4) newly recognized aspects of risk mitigation.

Remote Working

The immediate pandemic lockdown saw a seismic shift to remote work, with SME network companies seeing the greater potential for permanent changes in schedule flexibility and work-at-home accommodations. The overall shift is consistent with, if not more dramatic than, the longer-term pattern seen across business sectors. Choudhury²⁸ identified a number of benefits from a work-from-anywhere model from a 4- to 5-decade pre-COVID-19 experience, with better quality of life, reduced cost of living, and greater productivity as leading features. In a McKinsey survey taken across business sectors in the middle of the COVID-19 pandemic, LaBerge and et al²⁹ found that the most marked increase in response to COVID-19 disruption was in remote working. Parker et al³⁰ found in their survey that for workers who say that their jobs can be performed mainly at home the transition to remote working is persisting as the pandemic has abated and that the impetus for remote working has shifted from being of necessity during the pandemic in 2020 to becoming a choice in early 2022.

Employee Well-Being

SME network companies also identified employee mental health and well-being as of greater concern than did LE network companies. Harju et al³¹ recently characterized 5 well-being profiles among employees during the first lockdown based on a survey conducted in France and the United Kingdom: moderately positive (67%), languishing (18%), flourishing (8%), mixed feelings (4%), and apathetic (3%). The greater concern for well-being identified in SME network companies may reflect a different mix of profiles than for LE network companies. Regardless of the varying degrees of well-being and mental health, this survey reveals the general concern across the industry and contributes to the transparency, although consensus and accompanying policy responses are not yet within reach.

Strategic Priorities

LE network companies valued strategic priorities as having the greatest difference in assessment from that determined by SME network companies. This finding may possibly be related to the greater extent to which LE network companies are global. Jimenez³² describes the global nature of companies' responses to regulatory authorities to meet case management, signal management, and benefit-risk management requirements in a timely way. Furthermore, Jimenez³² emphasizes the roles of the pandemic in pushing the PV function to innovate. Ferreira-da-Silva et al³³ propose a comprehensive, 6-axis guide that intensifies case management activities to meet the challenges posed by COVID-19.

Automation is a recurring theme identified in the survey in multiple categories, including strategic priorities, workload changes, ICSR compliance changes, and PV technology strategy. It became a significant case management issue because of the substantial increase in case reporting during the pandemic. Commercial database vendors have taken note, as one vendor has advertised: "The next domino: automation, AI [artificial intelligence] and touchless safety case processing."¹²

Importance of Newly Recognized Aspects of Risk Mitigation

The long-standing business thematic expectation of continual, usually incremental, enhancement of efficiencies that predates the COVID-19 pandemic is based on the already recognized economic benefits

from the mechanization of highly routinized processes. However, the COVID-19 pandemic has brought important further awareness of newly recognized aspects of risk mitigation of potential, strategic, and usually uncommon scenarios that have long been appreciated in other business sectors and that now need to be considered in PV business continuity planning processes.

Initially, regulatory risk was quickly and generally recognized when early pandemic lockdowns led to markedly restricted travel that, in turn, impaired on-site activities needed to file time-sensitive documents. Global companies experienced the additional complication of reduced commercial air travel that resulted from cancelled flights, which imperiled timely inspections and consequently put at risk timely product approvals. There quickly followed recognition of the value and importance of local, back-up resources to provide protective redundancy against unanticipated events to balance the lean organizational drivers currently in vogue that led to economic and competitive risks associated with efficient, though bare, processes. Thus, just as the application of artificial intelligence can be expected to accelerate innovative processes, as with the increasing sophistication of databases,¹² so too can risk mitigation, under the guise of built-in redundancy, be expected to be a component of the rationale for a more broadly defined and better informed application of efficiency measures.

Implications for a Path Forward

Our survey makes clear the essentially ad hoc, reactive nature of both LE and SME network companies' PV responses to the pandemic disruptions and underscores the need for a greater proactive component of the contribution of PV to enterprise continuity planning. Together, these thematic findings can serve as action items for PV managers in drafting their business continuity plans: (1) continue to leverage automating technologies, especially artificial intelligence-enabling technologies, at all PV operational levels, especially for ICSR management; (2) use virtual meeting formats as primary go-to technology for routine communications that do not necessitate high-stakes, in-person meetings, including, for example, clinical trial subject recruitment, monitoring, follow-up, and data collection; (3) mitigate global risks (eg, pandemics and wars) with redundancy and fallback planning models; (4) stay current with regulatory agencies' guidance documents

on contingency planning; (5) practice moot scenarios and identify planning gaps; and (6) conduct regular reviews of contingency plans.

These high-level actions find grounding in the work of Margherita and Heikkilä,³⁴ who created a COVID-19 response framework from their analysis of 50 global companies and identified 77 actions related to 13 subareas across 5 work components (operations, customer, workforce, leadership, and community responses). The greatest number of actions (29 actions) were identified under workforce and human capital, stressing the importance of reducing the negative effects of the pandemic and taking advantage of the opportunities to enhance human capital.

Limitations

As with earlier industry PV surveys,³⁵ pvnet and pvconnect are self-selected, member-only organizations that are largely limited to the United States and the European Union, and they may be affected by internal and external pressures, such as mergers and acquisitions. Questions were intended to be a condensed view of the cumulative first-year of experience on the relevant activities that were taking place early in this fast-moving pandemic. Elicited responses included a substantial degree of subjective, qualitative assessments that necessarily led to less precise assessments, and the responses were based on the best available information from managers with variable degrees of experience and professional sophistication that included an unknown degree of bias, all of which should be kept in mind in determining the generalizability of the findings.

Even given the limitations, this analysis remains important because PV is often treated as a cost center and is generally underfunded in resource allocation and understaffed, particularly in seasoned professionals, yet it is critical to a company's organizational health and to maintaining its products' safety profiles.

CONCLUSIONS

Both LE and SME pharmaceutical companies reported substantial, although not unexpected, effects of the COVID-19 pandemic on their PV functions, although in different ways. SME companies reported greater impact than did LE companies on shifting to remote work and on employee well-being, whereas LE companies reported greater impact on all other measured functions, most notably on strategic priorities.

DECLARATION OF INTEREST

P. Beninger: Receipt of financial support for authorship and publication of this article from the department of Public Health & Community Medicine at Tufts University School of Medicine. P. Caubel and G. Pajovich: Receipt of financial support for authorship and publication of this article from Pfizer Inc. L. Sharma: Receipt of financial support for authorship and publication of this article from Navitas Life Sciences. P. Boyd: Receipt of financial support for authorship and publication of this article from Navitas Life Sciences and ResMed Ltd. The authors have indicated that they have no other conflicts of interest regarding the content of this article.

Given his role as co-Editor-in-Chief, Paul Beninger had no involvement in the peer-review of this article and has no access to information regarding its peer-review. Full responsibility for the editorial process for this article was taken by Jill Maron, co-Editor-in-Chief.

ACKNOWLEDGMENTS

We thank Mamtha Balakrishnan Nair for her editorial support in reviewing the manuscript. All authors contributed to the study conception and design. Data collection and analysis were performed by Latika Sharma and Pete Boyd. The first draft and reviewer-directed revisions of the manuscript were written by Paul Beninger, and all authors commented on previous versions of the manuscript. All authors read and approved the final and revised versions of the manuscript.

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