
PROCESSING OF INDIVIDUAL CASE SAFETY REPORTS IN THE PHARMACOVIGILANCE DEPARTMENT OF INDONESIAN VACCINE COMPANIES

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ABSTRACT

This study aimed to determine and analyze the processing design of individual case safety reports in Indonesia's pharmacovigilance department of vaccine companies. This study combines qualitative and quantitative studies that propose implementing the new artificial intelligence system for the PV Department. The results obtained from this study are problem-solving solutions by increasing the number of staff, using artificial intelligence (AI) technology in AEFI case processing to avoid errors and manual input, and approaching external stakeholders to be able to report safety data efficiently and more structured. With the addition of human resources to process the AEFI reporting data by one person, performance value will be increased to 165%. If the process utilizes AI technology, case processing performance increases to 219%. disruption of the performance of the pharmacovigilance department in Indonesian biopharmaceutical companies can be caused by the pandemic disrupting the way KIP cases are reported, so the solution is the addition of human resources, changes in processes and SOPs, as well as approaches to external stakeholders to streamline case processing.

Keywords: business process management, operation management, performance management, pharmacovigilance, vaccine.

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INTRODUCTION

The current condition of global health security is facing challenges in the Corona Virus Disease 2019 (COVID-19) pandemic (Rosyanti & Hadi, 2020). The pandemic forces us to quickly adapt to the course of the COVID-19 disease, including providing the COVID-19 vaccine (E. E. Otenyo, 2023). In the exploding number of the vaccination program injection, the vaccine industry also faces growth in adverse events following immunization (AEFI) reports (Hadinegoro, 2016). The pharmaceutical companies that hold the marketing authorization of the vaccine have the obligation of pharmacovigilance (PV) activities. AEFI reports received by an Indonesian state-owned biopharmaceutical company significantly increase from the regular vaccine report. In 2021 the adverse events following immunization reports for the COVID-19 vaccines reached approximately 15.088 case reports, including 316 serious cases of adverse events following immunization. This data is increasing significantly from previous years due to many COVID-19 vaccinations that began in early 2021.

The AEFI processing by the Indonesian biopharmaceutical PV Departments is conducted manually. The case is processed from the Individual Case Safety Report (ICSR) retrieval from the healthcare workers, data confirmation, and data input to the internal PV application until the case reports undergo causality assessment. The archiving process uses the pharmacovigilance application developed by an Indonesian biopharmaceutical company. However, the function is limited to only

the data archival and reporting without the ability to generate reports automatically and still needs to input the case details manually.

This study utilizes Business Process Management to resolve the problem in the organization. Business Process Management (BPM) is a systematic approach to improving and optimizing the processes within an organization (Nugraha et al., 2019). It involves process identification, process discovery, as-is process modeling, process analysis, process redesign (or process improvement), process implementation, and process monitoring and controlling to increase efficiency, reduce costs, and improve overall performance (Marlon Dumas, 2013).

This study's purpose is to define the root cause of the pharmacovigilance department in 2021 and explore the possibilities of problem-solving using business process management (BPM), including the root cause analysis of the problem and the study of the PV business process modeling. The solution proposed in this study is according to the BPM methodology in improving the business process, which includes process identification, process modeling, process analysis, process redesign/improvement, process implementation, and monitoring and controlling.

From the BPM process, we identify the benefit of artificial intelligence as a novel solution for improving pharmacovigilance case report processing. With the other solutions' synergy, the PV case processing improvement can be increased to 219% case processing capabilities in 30 days from the previously 80.70% performance measurement.

METHOD

This study combines qualitative and quantitative studies that propose implementing the new artificial intelligence system for the PV Department. The methodology of this research includes the internal and external situational analysis, started by collecting the supporting data, analyzing the internal and external factors that are influencing the business process of the PV Department by current SOP and protocol analysis, analyzing the current status of the business process in the PV department, analyze the preferred condition that aimed to be the goal of the improvement, examine the gap between the current and preferred state, analyze the root cause of the problem and propose the improvement using the Business Process Management (BPM) with the phase of process identification, process modeling, process analysis, process improvements, and also monitoring and controlling.

To collect the information, a semi-structured interview was conducted in this research with selected personas who play a role in the pharmacovigilance case processing, including the one who reviews and approves the case processing. The stakeholder identification and stakeholder analysis are also conducted to narrow down the people or organizations involved and have an influence on internal case processing activities.

RESULTS AND DISCUSSION

Business Process Management

Process Identifications

In this phase, business problems are identified. The analyst is trying to map the issue of the organization and taking measures to identify the root cause analysis of the problem—the process includes internal and external analysis (Stakeholder analysis, SWOT analysis, and POPIT Model).

SWOT analysis is often used to identify the elements that influence the organization and the business process of the organization. The components in the SWOT analysis are the Strengths, Weaknesses, Opportunities, and Threats (Cadle et al., 2010). POPIT Model defines process, organization, people, and information/technology to analyze the internal factor affecting pharmacovigilance case processing (Nuraeni Sayuti, 2013). The outcome of process identification is a process architecture that provides a helicopter view of the organization's process and the relationship between every factor that influences it.

Process Modeling

Process modeling in Business Process Management (BPM) visually represents a process using flowcharts or process maps (Mendling et al., 2013). This study utilizes Business Process Model and Notation (BPMN).

Process Analysis

Process analysis refers to examining and understanding a business process's current state to identify improvement areas (Rashin & Ghina, 2018). Process Analysis includes identifying the problem's root cause using the Current Reality Tree (CRT) and Performance Measures of the process performance dimension to calculate the work cycle time in pharmacovigilance case processing.

Process Improvement

Process improvement refers to changing a business process to increase efficiency, reduce costs, and improve overall performance. Process improvement aims to optimize the process to meet organizations' and customers' needs (Pelanggan, 2013).

Process Implementation

Process implementation covers organizational and process automation. In implementing organizational change management, we conduct activities that are required to change the way of working of all operators in the working process. Process automation means developing improvement in the IT sector that supports the current system to be more efficient and increase productivity (Salas et al., 2022).

Monitoring and Controlling

Monitoring and controlling a process refers to measuring and monitoring the performance of a business process and taking corrective action as needed to ensure that the process is operating effectively and efficiently. The goal of monitoring and controlling is to ensure that the process meets the organization's and its customer's requirements and that any deviations from the expected performance are identified and addressed on time (Sugiyanto, 2016).

Data Collection Method

The data gathered included primary and secondary data. The primary data is collected directly by the researcher, and secondary data is the data that can support the research developed by others in the past. The primary data gathered in this research is the aspiration gathered to the user of the process improvement, such as in the Pharmacovigilance Department, Surveillance and Clinical Research Division, and related stakeholders such as the Quality Assurance/Regulatory Affairs Division and Human Capital Division. The data was gathered using the semi-structured interview to collect the stakeholders' aspirations in improving the case processing improvement. The secondary data is collected using existing literature, books, journals, and articles to develop the analytical Framework from the previous study and the conceptual framework defining the desired process

improvement based on the state-of-the-art implementation. The conceptual Framework of the study is described in Figure 1.

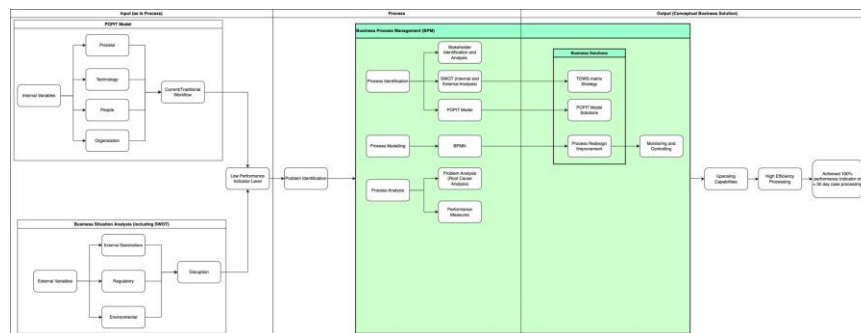


Figure 1. Conceptual Framework of the improvement in the pharmacovigilance case processing.

From Figure 1 above, this study uses the Input, Process, and Output (IPO) framework to design the conceptual framework for this study. To identify the causality network of the problem and the premises that can affect the output in the Pharmacovigilance Department case processing, we need to review back to the case processing of the Department.

Process Identification

The process includes stakeholders' identification and analysis, SWOT analysis, and POPIT model analysis to describe the input or as-is condition of the Indonesian biopharmaceutical company pharmacovigilance department. The results of the stakeholder analysis the plotted into the power and interest grid analysis, as stated in figure 2. Diagram of Stakeholder Quadrant of Power and Interest. The business situation analysis is also being conducted by SWOT analysis and POPIT model analysis described in table 1 SWOT analysis and table 2 POPIT Model. The process identification also locates the process problem and supports the root cause analysis described in the Process Analysis phase. The identification of the internal and external situational analysis using the SWOT was modified to acquire the TOWS matrix to formulate the strategic problem solution.

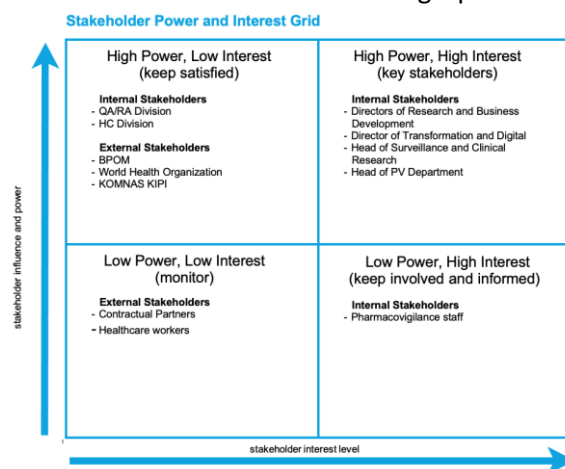


Figure 1. Diagram of Stakeholder Quadrant of Power and Interest

Figure 2 above describes the stakeholder analysis result and divides the stakeholders based on their power and interest in the project. From the analysis above, we conclude that the internal

stakeholders that have the high interest and high power to support the project of the case processing improvements are the Director of Research and Business Development, Director of Transformation and Digital, Head of Surveillance and Clinical Research Division and Head of Pharmacovigilance Department.

Table 1. SWOT Analysis

Strengths	Weaknesses
• Strong role in the vaccine development timeline after the vaccine is marketed. • An important role in the fulfillment of vaccine regulatory requirements • Strong partnership and collaboration in the post-marketing surveillance and other pharmacovigilance activities both with domestic and foreign partners • Utilization of PV application used in the archiving of the AEFI and ADR database to build the Pharmacovigilance System Master File several competent personnel (currently three staff, one head of department, and one head of Division)	• High cost associated with internal PV case processing • A limited number of personnel • Inefficient and complex SOP and multiple internal stakeholders • Inefficient and not digitally organized work documentation (manual case input) and archiving in the in-house PV Application and their limited features in streamlining the case processing. • High waiting time for the case processing • High workload as the staff does more than just the case processing in their job. • Dependencies to the strict qualification of the pharmacovigilance personnel • Budget constraint in human capital development, staffing, and application development (Human Capital Division is reluctant to increase PV Department staffing)
Opportunities	Threats
• Support from other Division within the company, especially QA/RA • Advancement in PV application technology using AI and NLP. • The potential of the PV application to be used in pharmaceutical SOE holdings subsidiaries and further developed as Software as a Service (SaaS) to other pharmaceutical companies. • Improvement of the case processing SOP with internal and external stakeholders, including harmonization of the case processing report format • Competency improvement opportunities by training the PV personnel to increase work efficiencies. Increasing the number of qualified PV personnel	• Vulnerability to changes in government policies and regulations. • Multiple external stakeholders that cause inefficiencies in case of processing (increase in waiting time) • Nature of the AEFI/ADR reports that is usually unstructured and in a different format • Vastly changing global health conditions such as pandemics • Complex nature of case processing causing application development harder.

In table 1 above, The SWOT analysis describes the internal and external condition of the organization that can be discovered from the internal and external analysis with the data gathered from several sources, such as the semi-structured interview, analyzed to know the actual condition of the working environment and internal business process analysis by collecting SOP data.

Table 2. POPIT Model

Factors	Problem Observed
Process	• Inefficient manual input of case processing • High waiting time for case processing • The nature of the reports received could be more structured. • The high number of case reports in the pandemic situation
Organization	• Inefficient and complex SOP • Multiple internal stakeholders • Budget constraints in human capital and improvement development • The Human Capital division is still reluctant to increase the staffing in the PV Dept
People	• High requirements of pharmacovigilance staff • High salary and investment for training • The low number of available qualified personnel for the PV staff
Information/Technology (IT)	• No automated features of the Bio Farma current PV Application • High budget for application improvement and development • Complex requirements and compliance in the business process make application development is harder

Table 2 describes the framework used in this study to analyze the input of the organization based on the process, organization, people, and information/technology or POPIT modeling.

Table 3. TOWS Matrix Formulate the Strategic Problem Solution

TOWS Matrix	Strategy
Strength/Opportunity (SO): utilize internal organization strengths to exploit external opportunities:	• Strengthening the synergy between internal units in the company to support the post-marketing vaccine development role and regulatory requirements (especially with QA/RA) • Strengthening the support from partners and regulatory institutions to build the harmonized AEFI/ADR report to be more structured and easily inputted. • Utilization of advanced technology in the pharmacovigilance system application to improve the current PV application • Human resources recruitment and training of the personnel to be fully competent and efficient
Weakness/Opportunity (WO): overcome the weakness and seize the opportunity available	• Support from other Divisions to prioritize the budget for improving the PV unit case processing. • Synergy to develop a more streamlined SOP of PV case reporting, including direct utilization of the PV app by the QA/RA Division • Integrating advanced case processing technology to add the limited features of the PV application to be more efficient and organized in the case intake. • Improve the case reporting by external stakeholders (Komnas KIPPI) to be more structured and complete and reduce the waiting time. • Additional staff to reduce the work burden

TOWS Matrix	Strategy
Strength/Threat (ST): exploit internal strength to overcome the threat from external	- PV Department has a significant role in the national healthcare resilience in the vaccine post-marketing safety data and activities. Synergy with the regulatory institution can make pharmacovigilance activities easier. - Strengthening collaboration with contractual manufacturer partners reduces the risk of competitors taking up the company's market share. - Efficiencies in the case processing activities can make the data and safety information easier to study and communicate with external stakeholders. - Utilization of advanced technologies can flexibly adapt to the ever-changing pharmaceutical industry regulatory requirements, locally and globally. - Opportunity to develop and improve the PV application as a SaaS to be implemented in the pharmaceutical holding company subsidiaries and other pharmaceutical company - API Integration of the current BioFarma PV application can make case processing with new technology more accessible to develop
Weakness/Threat (WT): overcome the weakness and seize the opportunity available	- Budget increase improving the PV unit capabilities to overcome the uncertainty of the regulatory and government policies. - Efficient case processing by synergy with the external stakeholders to develop a more streamlined process and reduce waiting time.

From table 3 above, we can conclude that the strategy can be taken in problem-solving by analyzing the elements in the SWOT strategy. The TOWS matrix strategy above formulated the solution strategy based on the organization's strength/opportunity (SO strategy), weakness/opportunity (WO strategy), strength/threat (SO strategy), and weakness/threat (WT strategy).

Process Modeling

Process modeling in the individual case processing of the pharmacovigilance in an Indonesian biopharmaceutical company using BPMN is described in Figure 3, Business Process Modelling and Notation of Case Processing in the Pharmacovigilance Department.

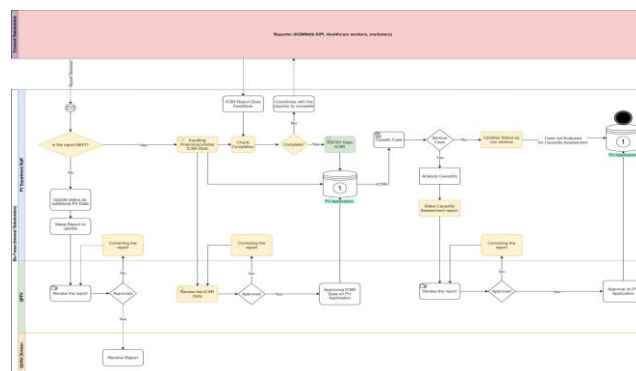


Figure 2. Business Process Modelling and Notation of Case Processing in the Pharmacovigilance Department

Figure 3 above describes the process of as-is case processing, which starts with case retrieval until the case is finished to be analyzed and stored in the pharmacovigilance department's PV application. The case processing takes a manual input method, and we can analyze in the picture above that the process is inefficient.

Process Analysis

Process analysis can be divided into qualitative and quantitative process analysis. The qualitative process analysis is conducted by the root cause analysis of the case processing performance impairment using CRT. This analysis is formulated based on process identification and modeling. The CRT diagram is described in Figure 4. Current Reality Tree analysis in the Pharmacovigilance Department.

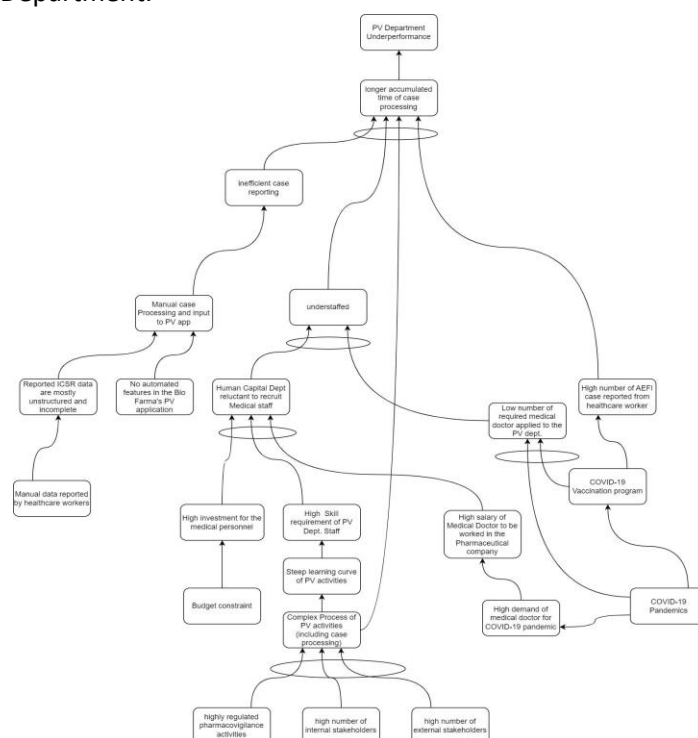


Figure 3. Current Reality Tree analysis in the Pharmacovigilance Department

Based on Figure 4 above, we can conclude that the root cause of the underperformance of the PV Department is based on several factors. The factors include external and internal factors. The quantitative analysis is the performance analysis of the pharmacovigilance department using the Key Performance Indicator (KPI) calculation based on the number of cases successfully processed within 30 days after the PV Department retrieves the case minimum preferred achievement is 90%. In 2021, the KPI achievement was only 80.70% due to the sudden increase in case reports received during a single day. Currently, the case report processing is limited to only the serious AEFI cases due to the insignificance of the non-serious AEFI cases to be followed up. In 2021, from 316 serious AEFI reports accepted, 61 reports (19.30%) were completed in more than 30 days. The average number of case processing days is 37.19, with a standard deviation is 37.74 days. The processing time of the case ranged from 1 day to 193 days. The variability of the case processing cycle time is primarily due to the variability of the case report completeness. The report data is usually unstructured and only contains a scanned document. The staff must manually retype and input the case into the

pharmacovigilance database application. The detail of the case processing time data and performance is presented in Table 4. Case Processing Time of Pharmacovigilance Department in 2021.

Table 4. Case Processing Time of Pharmacovigilance Department in 2021

Number of cases	processing days (shortest)	total processing days by three staff (min)
114	2	76 days
	processing hour (longest)	total processing days by three staff (max)
	4	152 days

From Table 4 above, the processing time of completing individual case reports usually takes 2-4 days, with 50% of regular working hours allocated for the ICSR case reporting. If the working hour every day is 8 hours, the processing time of each ICSR is about 8-16 hours. These are the cycle time of standard case processing in the condition that data sent from the external stakeholders are complete. For the incomplete data, the processing time of each ICSR is varied. In 2021, the PV department received 316 cases of serious AEFI that need to be processed. We can calculate the approximate working days needed to process the cases in 2021. We assume that all data required for analysis in the case reports are complete and that all the staff receives the same number of cases to process. The case reports PV staff process in one year is 105,3 cases, or we round it up to 106 cases yearly. The estimated fastest accumulated working days for the case processing for each staff is 212. If we take the number of working days in one year as 260 days, the PV team can still finish the report 100% with slack days of 260 days-212 = 48 days for each staff to do additional waiting time.

At the time 2021, there was 114 serious ICSR case received in one day on 19 March 2021. This means that for all the 114 reports received on the same day, the staff should still finish the case processing in 30 days. The available staff for the case processing in the PV department is only three staff to do all the data collection of the ICSR and coordinate with the reporter about the validity and completeness of data, manual case input to the PV application, completing the data for the follow-up reports, and making causality analysis in the PV application. Below is the calculation of the ideal working time of processing 114 cases by three staff for 8 hours working time and 50% allocation of workload is going to the case processing, and the report condition is complete:

$$\text{Total Processing Days} = \frac{(\text{Number of Case} \times \text{duration of processing})}{\text{number of staff}}$$

The duration (days) of the case processing is allocated at 50% of the total working time in one day for case processing, and the number of staff is 3. From the formula above, we can calculate the entire processing days described in Table 4:

This concludes that processing 114 cases received in one day is impossible to have 30 days performance target. The above calculation is applied in the case of ICSR, assuming all the reports are complete. If the ICSR data is incomplete, there will be an additional waiting time to coordinate and complete the data.

Process Improvement

Process improvement includes the TOWS matrix formulated using the SWOT and POPIT model analysis in the Process Identification and BPMN in the Process Modelling. The process redesign or

improvement utilizes the heuristic redesign method applied to the business process in the BPMN by contact reduction, integration, activity elimination, adding extra resources, using specialists, and activity automation. The proposed process improvement in the pharmacovigilance case processing is described in Figure 5. BPMN Diagram of the Improved Process.

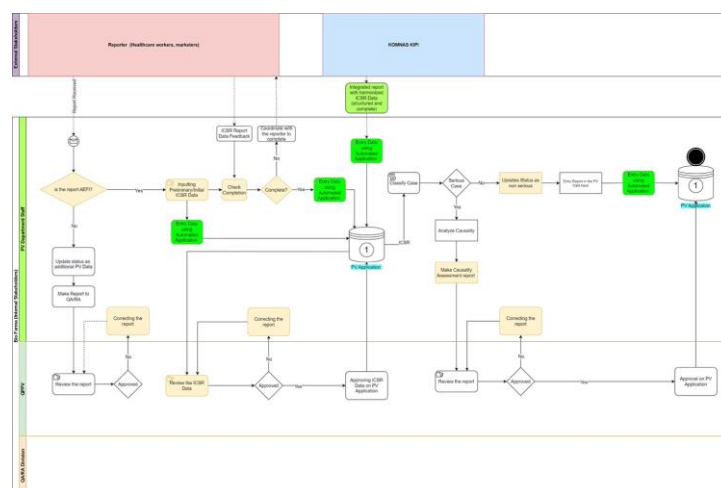


Figure 4. BPMN Diagram of the Improved Process.

Figure 5 above describes the proposed solution formulated in this study. The solution includes adding the staff and utilizing advanced case processing technology, including artificial intelligence.

Process Implementation

The process implementation is the transition phase of the as-is process to the to-be process and taking the preparation for the changes required (Aradea & Himawan, 2013). The aspects covering process implementation include organizational changes and process automation (Oracle, 2022). Corporate change management refers to the activities required to change the way of working for all stakeholders directly involving the process (Wibowo, 2021). These activities include:

1. Describe the changes to the internal stakeholders with the aim that the participants understand what changes are being implemented and why these changes are beneficial in the process improvement and improving the organization's key performance indicator.
2. Taking change management measures. The company was implementing change control in the operation of the company. This is the part of Good Manufacturing Practice commonly practiced in pharmaceutical companies. To maintain the quality, any changes in the SOP, including the new process and automation in ICSR processing, must be reviewed, and approved by Quality Assurance and Regulatory Affairs (QA/RA) Division.
3. Deployment and training to the user of the improved process to ensure a smooth transition to the new process

Process automation is another part of process implementation. Process automation utilizes information technology to develop and deploy the IT system that supports the to-be process. In this proposed study, the performance improved by using automation in the case intake to reduce staff workload by eliminating manual case intake and processing.

The early implementation phase is making boundaries or the requirements to define the improvement project's scope. From the interview with the Head of Surveillance and Clinical

research, the user requirement for the early adaptation of the implementation of AI and case processing technologies is in the automation of the case intake. By using AI, the unstructured data can be recognized and identified and input the case report form automatically to the as is the company PV application. Case intake is the process in pharmacovigilance that takes the most workload (50% of daily work hours) and most budget (40 % to 80% of the departmental budget) (Salas et al., 2022).

With the process automation implementation in case processing, the expected efficiencies are cutting the case processing cycle time. Oracle, an IT company, reports that the artificial intelligence pharmacovigilance platform can cut down individual case inputting to the application from 20 minutes to only 1 minute with 90% accuracy. The average processing time reduction in the case intake is up to 50% (Oracle, 2022).

Monitoring and Controlling

The monitoring and controlling phase of the BPM in improving the PV department can be conducted by measuring processing time and process quality. The measurement can of the time is focused on the time measurement of the case intake. The measurement must be displayed in the control dashboard to be quickly evaluated by the managers.

For the proposed improvement system, it is recommended that the evaluation of the total cycle time of case processing is divided into processing time and waiting time. Processing time refers to the time the system works to process the ICSR. Waiting time is measured by the system's idle time between the initial ICSR input and the follow-up report input until the ICSR is declared complete by the PV staff. The analysis of waiting time can be conducted as the justification if the new system's performance still needs to reach the preferred performance indicator.

Another process dimension is the number of days of individual ICSR case processing. The KPI of the PV department is stated as the percentage of cases processed within 30 days with a minimum of 90% of achievement of total ICSR finished processed. The system is expected to monitor the KPI calculation in real time.

The application's accuracy value measurement must also be documented in the application. The monitoring method of the application accuracy is by verification of the data correctness of the imputed report. The metric used is the number of correct prediction values of data inputted divided by the total data inputted.

$$Accuracy = \frac{\# \text{ correct ICSR inputted}}{\# \text{ total ICSR inputted}}$$

The AI's accuracy in the benchmarks by Schmider is expected to reach 79% of the correct prediction value (Schmider et al., 2019). This benchmark will be used as the basis of the quality performance indicator of the proposed application.

From the analysis above, the solution to the underperformance of the Indonesian biopharmaceutical company pharmacovigilance unit can be concluded into three main actions: the addition of human resources, the implementation of artificial intelligence in the case processing, and the approach to the related external stakeholders to make the case reporting more efficient and the data is more structured and complete.

Adding human resources to the PV department is the quick-win solution to problem-solving. Adding one personnel of PV staff can add the case processed approximately 65 to 130 cases per year. The below formula can calculate the whole processing days:

$$\text{Total processing days} = \frac{(\text{Number of Case} \times \text{duration of processing})}{\text{number of staff}}$$

Suppose we refer to the calculation of total case processing days in one year (260 working days per year) and assume that the average duration of case processing is three days. In that case, we can calculate the staff needed to achieve the performance index.

$$\begin{aligned} \text{number of staff} &= \frac{(\text{Number of the case in 2021} \times \text{duration of processing})}{\text{total processing in days in one year}} \\ \text{number of staff} &= \frac{(316 \times 3)}{260} = 3.64 \text{ or } 4 \text{ staff} \end{aligned}$$

This calculation shows that the number of additional staff for the PV department is approximately one person. The limitation of this calculation is that we assume that the data of the case received by the PV department is complete and that there is no waiting time for the case completion verification by the staff. The Head of Clinical Research approves the addition of human resources in the PV department. It is currently undergoing recruitment in the Human Capital Division.

The implementation of artificial intelligence can improve the processing time of case processing in the PV department. The expected performance of the application implementation is that it can reduce the processing time to up to 50% of the case processing cycle time (Oracle, 2022). The expected accuracy of the application to gather data from the unstructured report is 79% based on the literature benchmark. The performance is even better in some prominent vendors that reached 90% accuracy. Implementing artificial intelligence in the ICSR processing can also be realized soon as the cost for the PV application improvement is already budgeted.

As of 2021, serious case processing is reached 80.70% of the performance indicator, below the preferred indicator of 90%. In the proposed use of artificial intelligence utilization in the company's PV application, it is assumed that manual input by PV staff is eliminated so that processing time is reduced and the performance indicator is targeted to 100%. As from the literature review from Oracle reports, if the increased performance of the case processing cycle time is reduced to 50%, we can calculate the total case processing capabilities of the PV department (Oracle, 2022). The average processing day for individual cases by manual input is assumed to be three days. In the utilization of AI, it is becoming 1.5 days. Using the formula of total processing days, and if we assume the total processing days within one year is 260 days, the calculated number of cases that can be processed within one year are as follow:

$$\begin{aligned} \text{Total processing days} &= \frac{(\text{Number of Case} \times \text{duration of processing})}{\text{number of staff}} \\ \text{Number of case} &= \frac{\text{Total processing days} * \text{Number of staff}}{\text{duration of processing using AI}} \\ &= \frac{260 * 3}{1.5} = 520 \text{ cases per year} \end{aligned}$$

This means the performance of the case processing without the addition of the staff is increasing by 165%. Furthermore, the number of cases processed in the addition of staff is increasing by 694 cases per year (219% of case performance).

This performance can be further increased if the Komnas KIP is willing to increase the efficiency of the case reporting to the pharmaceutical company and make the report complete and more structured. Integrating their AEFI report website with the manufacturer's PV system to send the AEFI data directly to the manufacturer's PV system will eliminate the manual case reporting by their staff. The real-life example of the PV application integration with the government institution is already running with the integration of PV application to the Indonesian BPOM eMESO (electronic Monitoring Efek Samping Obat) website. This combination of the proposed solution will further increase the capability of case processing performance in the pharmacovigilance practice.

CONCLUSION

This study concludes that the impaired performance of the pharmacovigilance department in Indonesian biopharmaceutical companies can have several root causes, as we analyzed in the root cause analysis: The pandemic is disrupting the way AEFI case is reported. In the 2021 case, the PV department received 114 case reports in one day. This makes the target of the performance indicator impossible to reach by the PV department in its current state. A low number of staff in the PV department. The pandemic is also making medical professionals more focused on healthcare services than pharmaceutical companies to be pharmacovigilance professionals; for the staff of PV, a medical doctor is required as PV activities need a medical decision in the causality assessment. The nature of case reports from the reporters is usually manual and unstructured, making the case processing manually inefficient. Case processing in pharmacovigilance activities is a complex process for documenting pharmaceutical product safety. This makes the process's learning curve high and requires high-quality human resources, making recruitment harder. The SOP is becoming more complex as it must meet the regulatory requirements of local and global regulatory institutions. Budget constraint limits the working process adaptation in the pandemic situation. By identifying the root cause of the underperformance of the organization, we can analyze the solution. Then we can propose the best practices that can be applied to the organization. Human resources addition, change in process and SOP, and approach to the external stakeholders to make the case processing efficient is the solution that we can do based on the analysis of this study.

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