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Research factors that are critical (or critically important) in assessing effectiveness of the pharmacovigilance platform.

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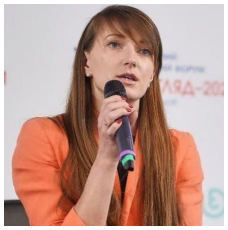

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Abstract

Factors that determine the effectiveness of the digital pharmacovigilance database are considered in the example of the development and analysis of the OtiPharm® Data Pro platform. Factors were divided into two groups: *highly specialized*, in which compliance with legal requirements for pharmacovigilance has the highest-priority; and non-specialized, that influence on the user experience of experts when working with the system. Such stages of pharmacovigilance processes as medicine safety data collection, processing and structuring and reporting to regulatory authorities are subject to automation. The task of the pharmacovigilance platform should be high-quality and convenient performance of its structuring and organizing functions, regardless of the type of internal process of working with information in the company. The base should become a convenient auxiliary tool and comply with the principles of ALCOA +. An effective pharmacovigilance platform allows devoting more expert`s time to implement product safety solutions, instead optimizing processes and functions that can be automated. The main parameter for assessing the effectiveness of digital platforms for pharmacovigilance is the change in the balance of the distribution of working time of specialists in routine operating processes to expert work.

Introduction:

In order to maximize the productivity of working time of pharmacovigilance specialists of pharmaceutical companies, cosmetics companies, manufacturers of food supplements, medical devices and veterinary drugs, we studied the factors that determine the effectiveness of digital pharmacovigilance database, using the development and analysis of OtiPharm® Data Pro platform as example.

First of all, we divided these factors in our study into two groups: *highly specialized*, in which compliance with the processes and procedures of pharmacovigilance as a system is of paramount importance; and *non-specialized*, that influence on the user experience of experts when working with the system, the quality and productivity of their work and flexibility - the speed with which the system and the people who work with it are able to respond to change.

We started working with the first group by studying the critical processes of pharmacovigilance, namely [1]:

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• continuous safety profile monitoring and benefit-risk evaluation of authorised medicinal products;

• establishing, assessing and implementing risk management systems and evaluating the effectiveness of risk minimisation;

• collection, processing, management, quality control, follow-up for missing information, coding, classification, duplicate detection, evaluation and timely electronic transmission of individual case safety reports (ICSRs) from any source;

• detection, investigation and evaluation of signals;

• scheduling, preparation (including data evaluation and quality control), submission and assessment of periodic safety update reports;

• meeting commitments and responding to requests from competent authorities, including provision of correct and complete information;

• interaction between the pharmacovigilance and quality defect systems;

• communication about safety concerns between marketing authorisation holders and competent authorities, in particular notifying changes to the risk-benefit balance of medicinal products;

• communicating information to patients and healthcare professionals about changes to the risk benefit balance of products for the aim of safe and effective use of medicinal products;

• keeping product information up-to-date with the current scientific knowledge, including the conclusions of the assessment and recommendations from the applicable competent authority;

• implementation of variations to marketing authorisations for safety reasons according to the urgency required

The introduction of an electronic platform significantly affects the efficiency of the company by simplifying the work of at least four of them.

For convenience, we have divided these critical processes into key stages:

* Continuous collection of data on the safety of the drug or product from various sources;

* Processing, analysis, evaluation and structuring of the received information, its coding;

* Reporting to regulatory authorities;

* Take all necessary measures for the safety use of the product.

Within companies, the service of the whole process is very different.

There are approaches where a specialist or department is responsible for the full cycle of working with product information from start to finish. Instead, in other companies, the work of pharmacovigilance is divided into different stages, for which entire departments are responsible, or branches-representative offices in different countries, already with their structure of the process.

Here we approached the second group of factors and analyzed how the usability of the digital platform will affect the quality of data processing.

Juhani Iivari, University of Oulu, in his study of the model of success of information systems, showed that the perception quality of the system by users is a predictor of its use, and statistically affects the efficiency of the system. Also, a group of authors, led by Jung-Fan Chen from the National Kaohsiung University of Applied Sciences, Kaohsiung, Taiwan, conducted a study that identified how the “attitude to use” factor will affect the model of information technology success. The results show that the “attitude to use” is significantly and positively influenced by perceived usefulness, perceived ease of use, and user satisfaction [3].

Thus, we concluded that the task of the pharmacovigilance platform should be the high-quality and convenient performance of its structuring and organizing functions, regardless of the type of internal process of working with information in the company.

The database should become a convenient support tool, not a new reform challenge for employees while complying with the ALCOA + principles developed by the FDA for working with information systems within its certification [4].

To solve these challenges, we have partnered with OtiPharm® Research, its specialists serve various pharmaceutical companies in the field of pharmacovigilance, writing medical reports, and also focus on regulatory procedures. 43 employees of the company have expressed readiness to advise our developers at the stage of creating a digital solution for pharmacovigilance, from ordinary pharmacovigilance specialists to QPPV of several pharmaceutical companies.

vision of the needs of all participants in the pharmacovigilance process in a pharmaceutical company.

The goal we set ourselves was to create an intuitive ecosystem that would be an organic continuation of the expert.

One of the criteria for its achievement, which we set, is the ability of the specialist to use the base from the first briefing and save time and human resources of the company spent on the implementation of the system.

We have identified this criterion as a predictor of synergy in the interaction between different departments of the company when working with information, and the level of users should vary from basic pharmacovigilance specialist or quality department to QPPV level

expert of the international company.

To solve such a complex task in the development of interface architecture, we have especially engaged specialists in UI / UX design, specializing in the methodology of Design Thinking and customer experience.

Analyzing among our experts, we found that from 25% to 45% of the time, and with it the attention, is lost when searching for the necessary documents, forms to fill out and consult and interact with other departments. At the same time, the risk that the specialist will switch to another aspect of the activity without completing the previous one, or choose a lighter less expert task, increases in proportion to the employee's level of fatigue and inversely proportional to the time until the end of the working day.

After a series of in-depth interviews with industry experts and research on the expert's user path, we have identified the key unit of work of the OtiPharm® Data Pro system - the "product card".

Its core is the documents of the product life cycle, and the elements - all available information about it.

When working with it, the specialist does not need to switch between different folders, documents and tables. All available information that the company has about the product is concentrated in it.

Even the literature search function, which is automated and built into the system, and in addition an integral and so important possibility of electronic exchange of information with regulators.

There is no need to leave the system and be distracted during focused activities.

Information moves along it from the periphery to the center, differentiating and becoming more complicated at each stage

The system is designed to ensure that the information in the collected messages is accurate, legibly written, accurate, consistent, verifiable and as complete as possible for its clinical evaluation.

All notifications containing pharmacovigilance data must be recorded and archived in accordance with current data protection requirements.

At the time of entry, the information should be immediately structured by the category to which it belongs, for example, such as a safety messages:

* unsolicited reports

- Spontaneous messages

- Reports from the literature

- Messages from other sources

* messages from sources with organized data collection system (solicited reports)

The designed fields are immediately carried out according to a special data entry algorithm and minimize the risk of error or incorrect input.

The duplicate verification process is automated at the application stage, and in case of suspicion signals about it.

Duplicate confirmation is performed manually.

To merge cases, a "master case" is created in the pharmacovigilance database [5].

Another critical process of pharmacovigilance is signals. Formulation of hypotheses about new possible adverse reactions is a process of ***signal detection.***

A special section has been created in the card for high-quality support of this process.

In this section, the notification of a suspected adverse reaction goes into a semi-automatic monitoring system and remains in this state, or proceeds to the next phase of approval in accordance with the information to be supplemented.

One of the most important functionality is ***appeals***. The appeals include information about any events related to the drug (quality complaints, adverse reactions, consumer complaints). In this case, the platform plays the role of an ecosystem shell, uniting cross functional experts in different fields (quality service, medical service, regulatory service, pharmacovigilance). The ability to conduct the necessary investigations concerning appeals, validation and transfer (if there are criteria) to adverse reactions provides an ecosystem at the level of the entire pharmaceutical company.

Flexibility. Reputation.

The company's reputation for the safety of its medicines is based on the ability to quickly and openly provide information to authorities and consumers.

Slow and inflexible processes can raise the suspicion of lack of transparency in the company's actions, or non-priority of security aspects.

At a time when the subjective perception of the risks of taking medicines by customers is growing, due to the attention to this topic on social networks.

The problem was that the offices of pharmaceutical companies could be located in different countries and time zones, and workers on business trips or at work did not always have immediate access to a computer.

The developers have solved this issue by continuous ***access to the platform 24/7*** not only from a computer, but also from a tablet or phone, with a special secure authorization.

Also, this approach allows QPPV and Regulatory Affairs to independently access any necessary pharmacovigilance information by monitoring it through the platform.

And the ***audit digital footprint*** shares and personalizes the responsibility for the work performed or data entered by each employee of the department.

To summarize the experience, we surveyed eight pharmaceutical companies that installed the investigated digital platform **OpiPharm®**

Data Pro with a total number of users - 88.

During this period of time of repeated appeals for additional consultations, 7 people applied for the use of the database. 6 of these users talked about the developed new unit before its presentation, and only one user needed additional advice on the main functionality of the digital platform.

The term of implementation of the database and the number of repeated requests for additional instruction were also studied.

Results and customer feedback.

Feedback from ***Liubov Kokoeva, Registration Specialist, STADA UKRAINE***.

The developers of the database claim that the implementation and transfer of data takes only up to two months. Is that true?

"Indeed, the implementation of the database took place within two months with the full transfer of all information on drugs and all adverse reactions."

And what are the impressions of managers from working with the database?

"Very convenient drug card, easy and convenient to work when all in one place. No need to search and open different folders and documents when generating a report."

Reviews of ***Oleksandr Torhun, the Regulatory Affairs Director of Darnitsa Pharmaceutical Company***:

Database developers claim that the implementation and transfer of data takes only up to two months. Is that true? How was the implementation in your case?

"All the obligations that OtiPharm® Data Pro LLC has undertaken in the framework of cooperation with the pharmaceutical company Darnitsa have been fully fulfilled. We would like to note the effective organization of the data transfer process: from the moment we submitted the completed forms, the data transfer to the system, the verification and implementation of the platform took three weeks instead of the expected two months."

How flexible are digital platform service providers? What modifications were made at the request of the customer?

"In order to effectively manage information about adverse reactions at an early stage, the developers have created an additional module "Appeals". The module fully meets our expectations and needs. Subsequently, during the operation of the "Appeal" module, it became necessary to create additional fields for data entry and the company-developer of the platform Otipharm® Data Pro performed this task more than a week ahead of schedule. This helped to accelerate the implementation of the new procedure in the company."

Conclusions: On the example of creating and working with the digital platform OtiPharm® Data Pro, we found that modern computational algorithms can simplify the activities associated with pharmacovigilance in stages:

collection:

- filter information;

- research in a semi-automatic mode according to the set criteria;

- receive messages pending processing by a specialist;

- accumulate undifferentiated information;

structuring and preliminary analysis:

- processing;

- management;

- quality control;

- identification of the necessary missing information;

- coding;

- classification;

- detection of duplicates;

- signal management.

information exchange:

- timely reporting of adverse reactions;

- sending reports;

- communication ecosystem solution:

    - opportunity to work with several cross-functional experts (quality, medical service, regulatory service, pharmacovigilance) with appeals
    - fixation of investigations on appeals
    - possibility to monitor the progress of investigations into appeals (complaints)

And the productivity of these processes is significantly statistically higher with a high perceived ease of use and user satisfaction.

Thus, we found that of the key stages identified at the beginning of the study, the first three are subject to automation and continuous improvement:

* Continuous collection of data on the safety of the medicines or product from various sources;

* Processing, analysis, evaluation and structuring of the received information, its coding;

* Reporting to regulatory authorities;

However, the last stage - decision-making, namely "Taking all necessary measures for the safest use of the product", remains the absolute prerogative of pharmacovigilance experts.

Based on this, we conclude that an effective pharmacovigilance platform allows us to devote more expert time to the implementation of product safety solutions, instead of optimizing processes and functions that can be automated.

The study revealed the main parameter for assessing the effectiveness of digital pharmacovigilance platforms - changing the balance of working time of specialists in routine operating processes (collection,

processing, entering information into the database) for expert work (risk assessment, development of new solutions and improvement of pharmacovigilance). Such a change in processes significantly increases the efficiency of individual specialists and the pharmacovigilance system as a whole and allows it to scale without involving a significant resource.

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