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Pharmacovigilance within Technic Solutions

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Commentary

Inception of harmonised regulatory requirements revealed an important step toward high responsibility for human health safety. The process of regulatory harmonisation goes along with constant simultaneous developing of safe solutions for routine activities. Even though, there is still an empirical collection of various experiences, without sharing of best practices would be the current progress not possible. Similar development undergoes drug safety comprising strategic and operative activities to support pharmaceutical companies to fulfil the responsibility for own products, for public health and for being compliant with the current regulations. Nowadays, drug safety gains more and more significance within “traditional“ activities of pharmaceutical companies: safe data collection, safe processing of the data, safe evaluation and assessment of reports, safe submissions to authorities, safe overview of time frames for periodic reports, safe signal monitoring, safe management of risks of medicinal products. Summarizing, we can speak from safe pharmacovigilance. But what does mean “safe”?

The term “safe” includes particularly not just only data privacy aspects or cyber safety. It should be understood more broadly, closer to the own definition. The term “safe” is attested from late 14c meaning "rescued, delivered; protected, "not exposed to danger" (of places).

Additional aspects to the meaning came in c 1600: "free from risk,

"sure, reliable, not a danger" and “sense of "conservative, cautious"[1].

How can we ensure that the concerned medicinal product and, to the great extent, a pharmaceutical company, is supported by safe pharmacovigilance processes? Human errors, communication-based issues, differences in time zones represent only a small range of challenges for responsible persons. Our approach is to outline some pharmacovigilance activities, which can be significantly improved by corresponding technical solutions.

Data Collection

This element of pharmacovigilance is a basis for all the collected knowledge about active substance. There are many ways for a pharmaceutical company or for contractual partners to collect relevant data about medical products and about their safety profile. There were many sourced to collect drug safety data. Some of them are of spontaneous nature. It means, the consumer and health care professionals can inform the concerned company directly by calling hotline, by writing of a letter, by email. Maybe it is possible to report an adverse drug event via virtual interface. Some reports are originated from solicited sources like Patient Support Programs (PSP), Marketing Research Program (MRP), non- interventional studies (NIS). Scientific literature is another source of data contributing to safety profile. Before marketing authorisation is granted, clinical studies deliver the data about safety profile of the medicinal product. In order to ensure that the maximum numbers of cases are collected, a certain number of processes and trainings are frequently implemented to encourage people to submit product complaints. But regardless of all these efforts, most of the patients and even healthcare professionals consider that only unexpected cases or expected cases occurring at a non-expected frequency or seriousness level should be reported. Technology may also be very useful here:

- Include a form on the company web site to ensure customers can report easily adverse reactions however a certain number of controls are then required to ensure all fantasist requests won’t be uploaded in the pharmacovigilance database.
- Use artificial intelligence in order to record cases automatically based on calls given to the call center.
- Explore the social networks to find potential cases-The main difficulty here is to ensure the data is real and the sender can be properly identified.
- Lots of e-health applications are developed; these applications could easily include a functionality allowing the patient or the doctor to send all required information when an adverse reaction occurs.
- Import directly the Adverse Events from the Clinical Trial Database into the Pharmacovigilance Database.
- Automatic search of cases in the literature.

However when implementing such technologies, it is also necessary to ensure that no duplicate case is produced.

Data Entry

After the data is received, triage is performed:

- Are there all necessary data elements available for a valid case?
- Does the case meet seriousness criteria?
- Is it already known reaction in accordance with e.g. Investigator Brochure or Company Core Safety Information/ Summary of Product Characteristics or is it somethings new?

An excellent tool for assessment of seriousness is provided in form of a list of important medical event (IME) terms, together with the criteria to facilitate its maintenance. The list aims to facilitate the classification of suspected adverse reactions as well as aggregated data analysis and case assessment for the day-to-day pharmacovigilance activities of stakeholders in the EU [2]. Depending on the pharmacovigilance database used to process cases, additional features may be available: customizable edit checks verifying the validity of data, automatic generation of narrative, and check for potential duplicates.

Quality Check

Recommendations on having of a "a quality management system in place to ensure compliance with the necessary quality standards at every stage of case documentation, such as data collection, data transfer, data management, data coding, case validation, case evaluation, case follow-up, ICSR submission and case archiving are clearly defined within Good pharmacovigilance practices (GVP), Module VI "Collection, management and submission of reports of suspected adverse reactions to medicinal products (Rev 2)" VI.B.5. Quality management [3]. The most conservative and safe approach by implementing or setting up of corresponding processes is to have an in-process quality check. There is data evidence of significant improvement of compliance (avoiding of late cases after corrections) and data quality (double check by another person). Even though the QC performed by a second person is usually a good method to ensure the accuracy of data, it is reasonable to build checklists, sometimes depending on the product, to ensure all data entered in a case is consistent. Such checklist may be automated either within the pharmacovigilance database or through external tools.

Narrative Writing

The narrative should reflect the provided data "as reported", but on a structured way. No interpretations are acceptable. It should reflect the data in a such way that every person, who did not see the source data, could exactly understand, what happened with the patient, what was the sequence of events, when did events occur, when was a suspected drug administered, what was a medical history of the concerned patient, what was a concomitant medication, which treatment did the patient received, what was the outcome and how was assessed the causal relationship by reporter?. From the view of multiple years of drug safety experience, we can say that a report is never one to the other. And, nevertheless, the unique story should be represented in a standardized way.

Submission of Adverse Event Reports

Even though, there is still a variety of reporting requirements on the international level, it is all the more need to be compliant with regulatory requirements.

Signal Management

Signal is defined as "information arising from one or multiple sources, including observations and experiments, which suggest a new potentially causal association or a new aspect of a known association between an intervention and an event or set of related events, either adverse or beneficial that is judged to be of sufficient likelihood to justify verificatory action" [4]. It is a duty and high responsibility of a pharmaceutical company to keep the knowledge about safety profile up to date. Signal Management is a most important tool, which enables to the pharmaceutical companies to manage the collected and assessed data in a way that new relevant safety information can be identified and appropriate actions can be performed. A useful tool for evaluating the benefits and risks of medicines during their development and monitoring their safety following their authorisation in the European Economic Area (EEA) represents The European database of suspected adverse drug reaction reports (adrreports.eu) [5]. It supports the signal management activities by giving access to web reports on suspected side effects. Adverse event reports are derived from EuDRA Vigilance database.

Additionally, it is interesting to use custom tools to review the data, particularly when precise coding processes are defined or if specific Adverse Reactions are inspected. There are various Data Analysis or Signal Detection applications allowing to review aggregate data, either as statistical evaluations or as graphs. Such tools are very useful for PSUR, PBRER, and Signal Management. The advantage of graphical views is that it usually improves a lot the review time, for statistics the disadvantage is that these review methods are not very relevant for small number of cases.

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