# **Digital Revolution in Pharmacovigilance**

Laura Eder<sup>1,5</sup>, Francisco Rodríguez<sup>2,5</sup>, Miriam Álvarez<sup>3,5</sup>, Sonia López<sup>4,5</sup> <sup>1</sup> Drug Safety Associate Director; <sup>2</sup> Drug Safety Officer; <sup>3</sup> Drug Safety Manager; <sup>4</sup> Pharmacovigilance Director <sup>5</sup> Pharmacovigilance Department. Asphalion SL, Barcelona, Spain



### INTRODUCTION

Artificial Intelligence (AI) or Machine Learning (ML) and Natural Language **Processing** (NLP) technologies are transforming today's resource-intensive workflows in the **healthcare sector** ensuring a more informed and efficient approach.

These technologies have great potential in **Pharmacovigilance** and could lead to a more efficient approach that would allow a **focus on patient safety**.

## **OBJECTIVES**

To evaluate **pharmacovigilance processes** for digitalization and to define a comprehensive criterion for the selection of software solutions.

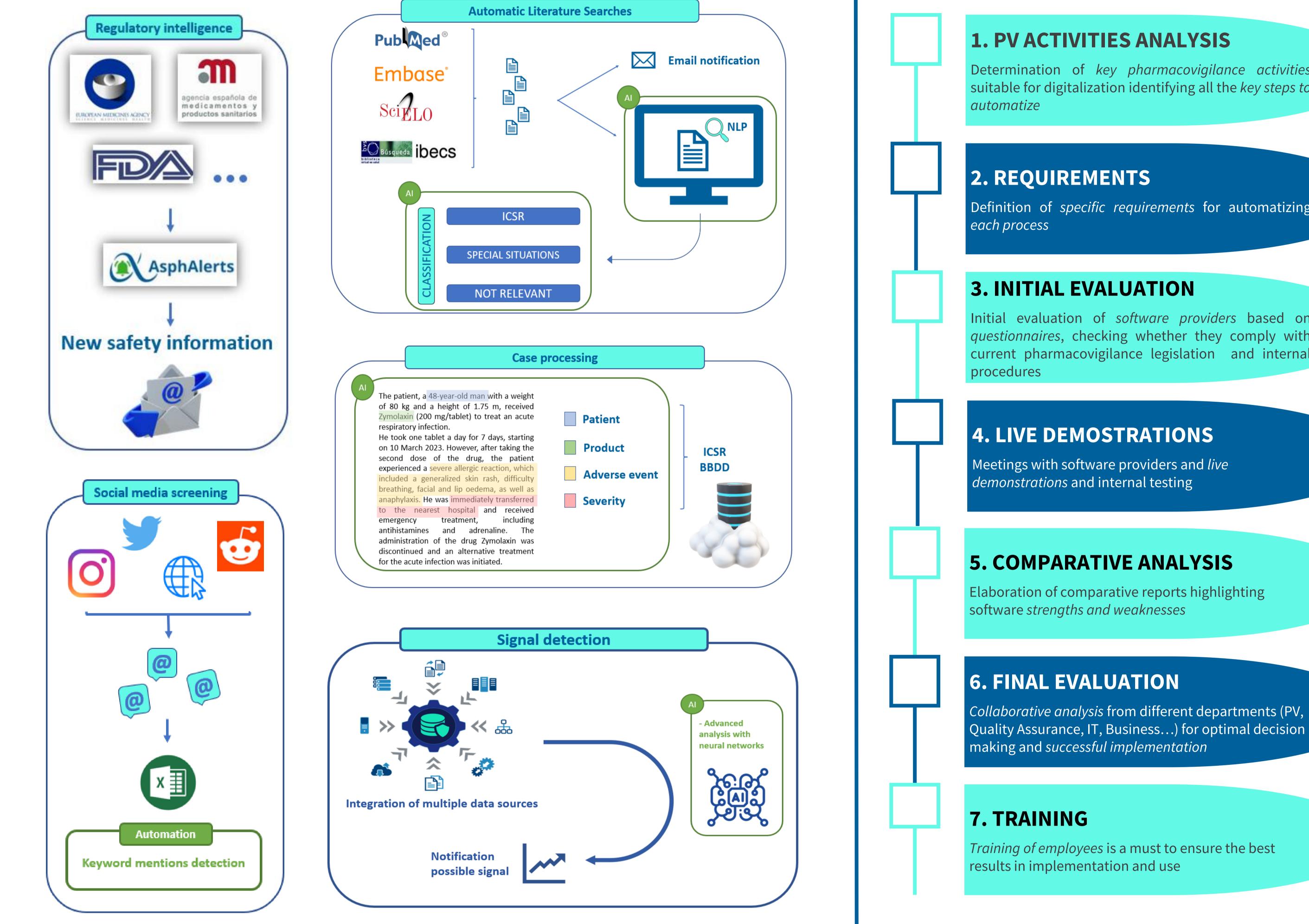
To explore new tools and technologies for the implementation of **digital solutions in pharmacovigilance** and to highlight the **advantages** of digitalizing a pharmacovigilance System.

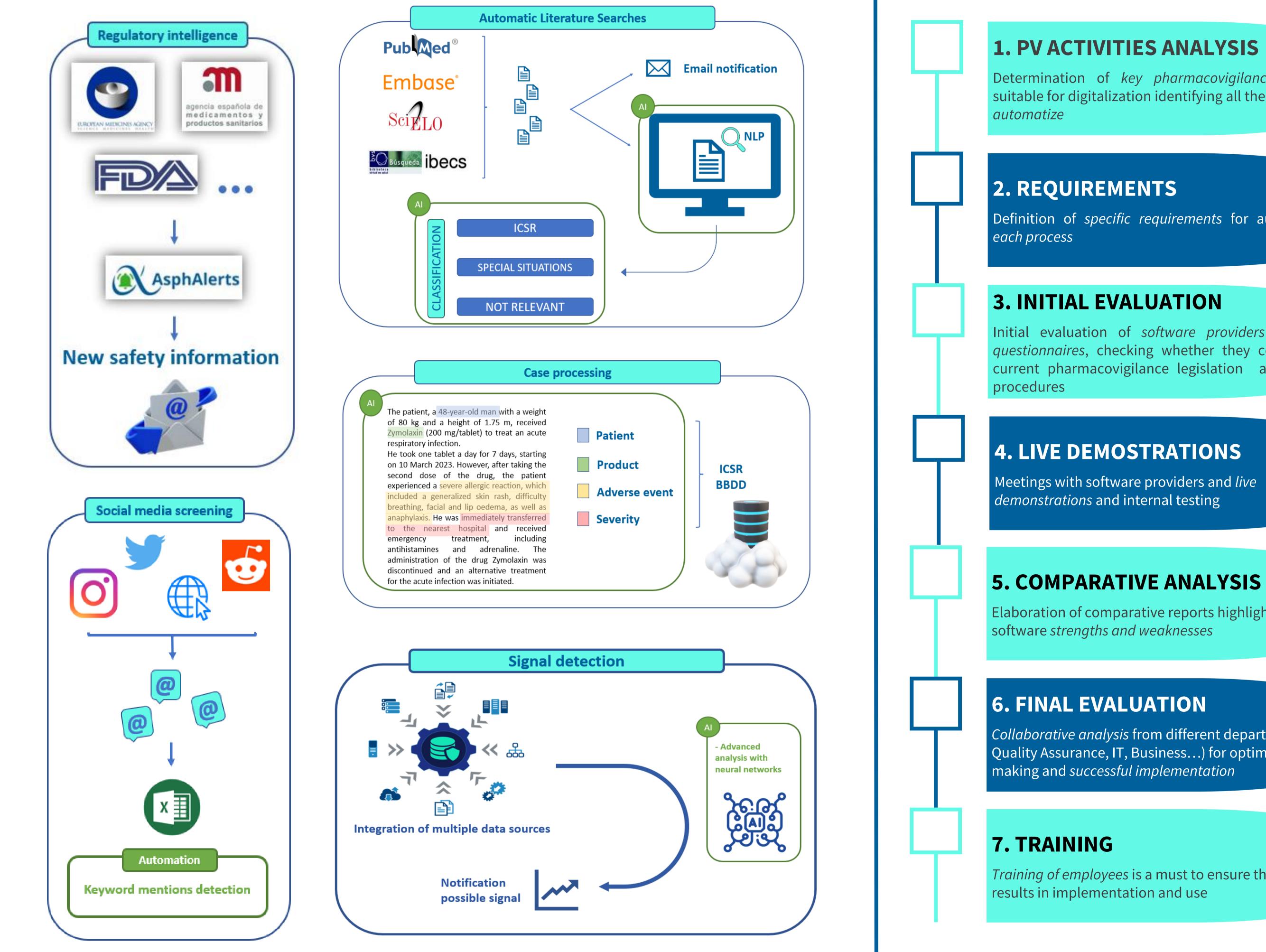
# RESULTS

# <u>Pharmacovigilance processes compatible with digitalization</u>

**Pharmacovigilance activities** that can benefit from the implementation of digital solutions are, but not limited to:

### **Software Selection and Implementation Model**





Successful digitalization in pharmacovigilance consists of:

Determination of key pharmacovigilance activities suitable for digitalization identifying all the key steps to

Definition of specific requirements for automatizing

Initial evaluation of software providers based on questionnaires, checking whether they comply with current pharmacovigilance legislation and internal

**Figure 1**. Illustration of how specialized software enhances five key processes in pharmacovigilance

*Figure 2.* Infographic of the digitization and software selection process

# CONCLUSION

**Digitalization in Pharmacovigilance** creates a **new scenario for safety assessment** supporting data analysis and allowing pharmacovigilance professionals to focus

**Digitalization in Pharmacovigilance** reduces human error and speeds up the process of identifying relevant safety data and risk assessment. It also plays an important role in the detection and classification of adverse drug reactions (ADRs) and enables rapid monitoring of competent authorities' websites for real-time alerts and updates supporting timely decision making.

Although challenges related to data protection or system updates must be considered, digitalization in Pharmacovigilance benefits healthcare professionals, patients and public health.



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