

## 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

### Pharmacovigilance processes compatible with digitalization

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

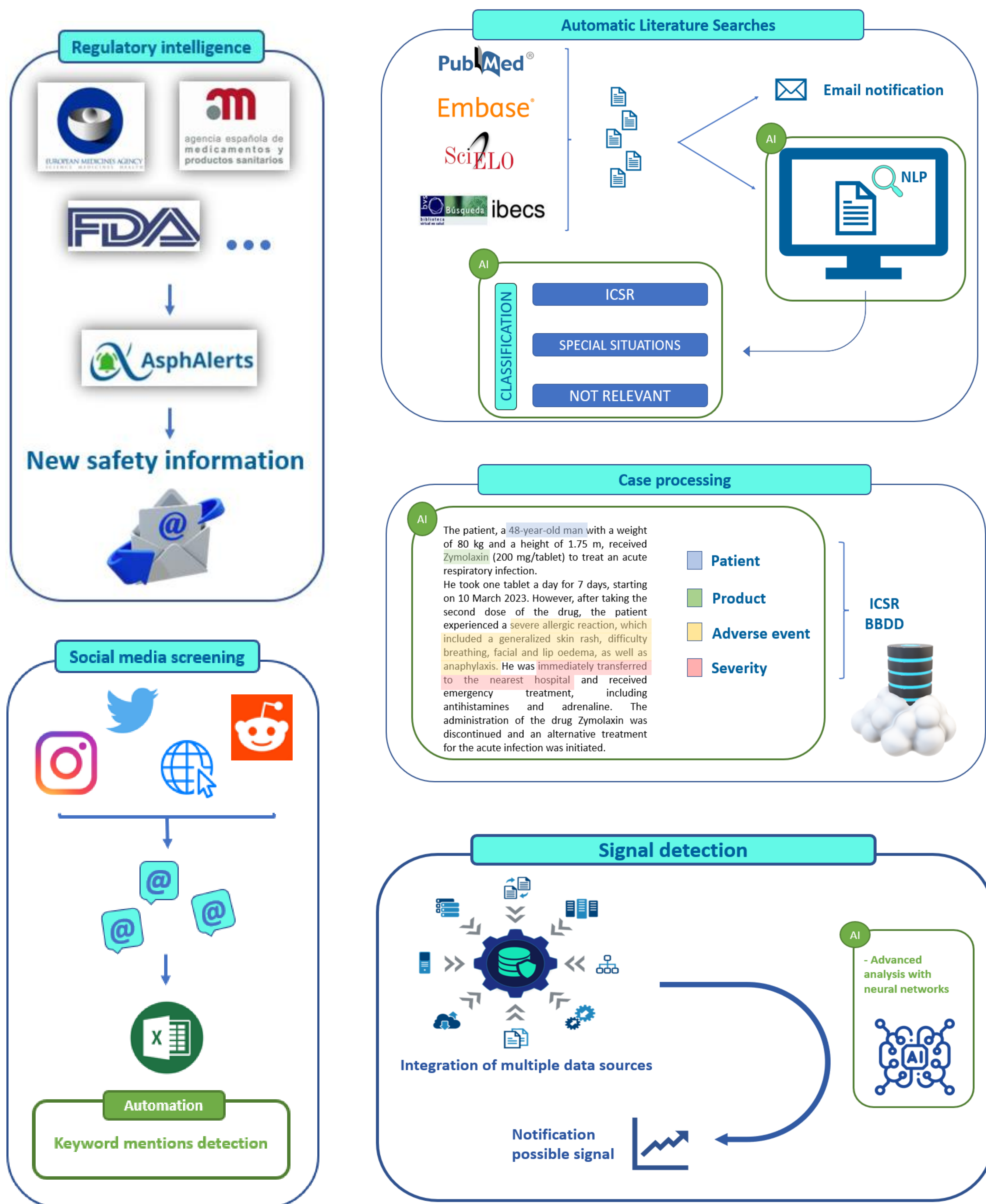


Figure 1. Illustration of how specialized software enhances five key processes in pharmacovigilance

### Software Selection and Implementation Model

Successful digitalization in pharmacovigilance consists of:

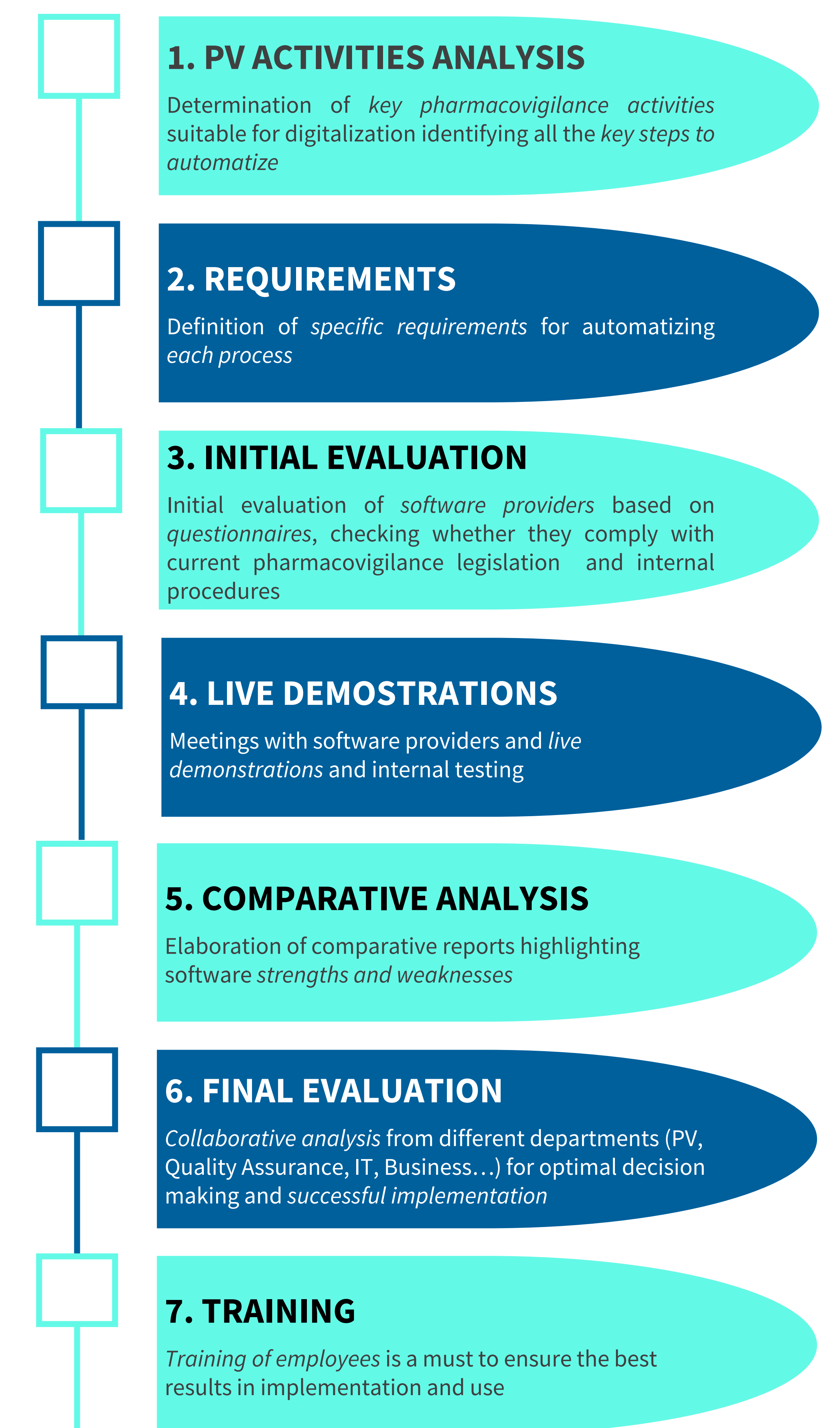


Figure 2. Infographic of the digitization and software selection process

## CONCLUSION

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

**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**.