

Bridging the Gap: The New Key Player in Digital Transformation and Pharmacovigilance

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INTRODUCTION

Digital tools in pharmacovigilance are increasingly valued for their **transformative potential**. Integrating these tools requires a strategic approach merging **technological capability** with **regulatory compliance**.

A **new key player**, focusing on pharmacovigilance and digitalization, **links software developers** and **traditional PV departments**, ensuring innovations are viable, safe, and compliant for a **seamless digital transformation**.

OBJECTIVES

1. To define the role of the **new key player** in **enhancing digital tools adoption within pharmacovigilance**.
2. To translate technological capabilities into **regulated, industry-specific solutions**.
3. To establish a **robust connection** between **digital providers** and **pharmacovigilance needs** for optimized processes and compliance.

RESULTS

Responsibilities

NEW!

Software Developers

- Expertise in digital tools and development.
- Lack specific knowledge in pharmacovigilance regulations.

Expert in Digital Transformation and Pharmacovigilance

- **Strategic support** providing a 360° view: pharmacovigilance, digitalization, and regulation.
- **Integration of digitalization**, automation, and big data in pharmacovigilance processes.
- Acts as a **strategic consultant**, guiding the pharmacovigilance department to full implementation and validation.
- **Connects** software development experts with pharmacovigilance teams.
- Offers **expert support** on new guidelines for digitalization in pharmacovigilance.

Pharmacovigilance department

- Expertise in patient safety and regulatory compliance.
- Lacks specific knowledge in digitalization and process optimization.
- Digitalization is not their primary focus.

Phased planning for PV digitalization with the support of the new key player



Preparation

Adapt SOPs and create governance systems for digital tools integration following up to date legislation.



Needs Identification

Determine specific areas where digital tools can add value.



Software Selection

Choose digital tools that meet regulatory and business needs.



Pilot Implementation

Test applications in controlled environments.



Validation

Ensure digital tools are accurate and compliant with standards.



Training and Support

Develop comprehensive training programs.



Maintenance

Ongoing support for digitalization, assistance with validations and continuous improvement.

New Key Player

CONCLUSION

Implementing **digital transformation in pharmacovigilance** and drug safety **significantly enhances efficiency** by automating repetitive tasks and **reducing human error**. This accelerates and improves pharmacovigilance processes, enabling more precise and reliable data management.

The presence of a **dedicated key player** that integrates a strong knowledge on both digitalization and pharmacovigilance greatly **accelerates** the **digital transformation in pharmacovigilance**. By translating and adapting digital innovations to **meet regulatory and industry standards**, this role ensures that **digital tools are effectively integrated into everyday practices**. This approach not only bridges gaps but also fosters a culture of continuous improvement and innovation.

By prioritizing **patient safety** and **leveraging digitalization**, a pharmacovigilance department is well-equipped to meet evolving demands with greater agility and confidence, ultimately leading to **enhanced patient safety** and **more efficient regulatory compliance**.