FORUM

Pharmacovigilance KPIs

Key Performance Indicators for a robust PV System

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Dear Reader

In the regulated but dynamic field of pharmacovigilance and quality management, the core principle remains unchanged: Monitoring, analysing, and interpreting results is essential for pharmaceutical safety and process efficiency. This paper focuses on the role of Pharmacovigilance Key Performance Indicators in strengthening drug safety quality and effectiveness. It covers the general context as well as its regulatory background

Interested in deepening your knowledge? In our interactive training „Pharmacovigilance Key Performance Indicators“ you learn to set up, measure and visualise KPIs in PV in practice. It also covers audit preparation, KPIs in partnerships and outsourcing, and real-world examples.

We wish you an insightful read.

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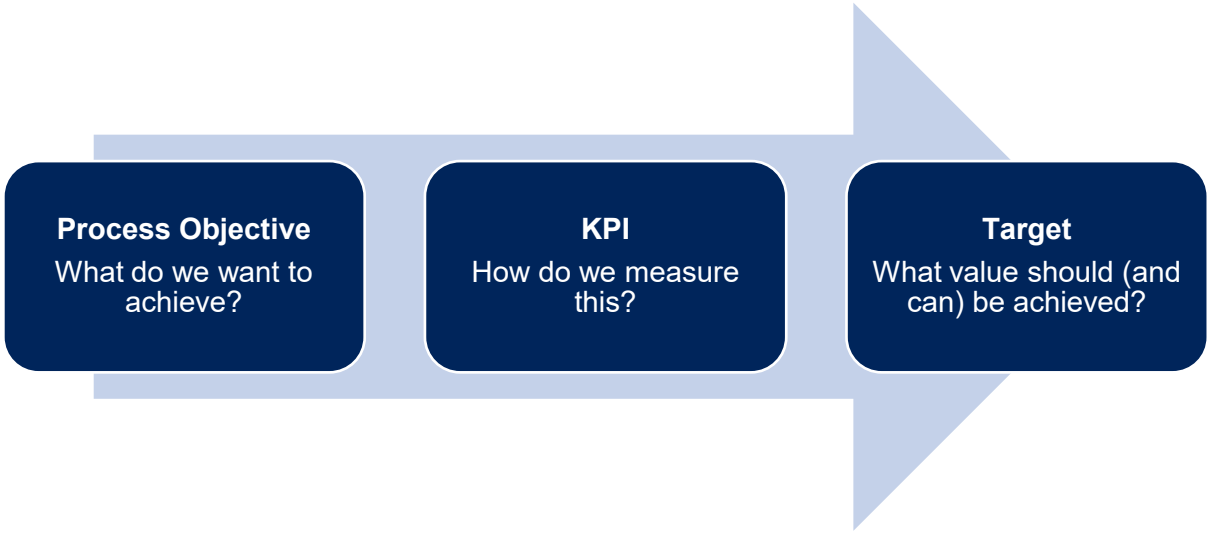
1. Basics of KPIs

1.1. What are KPIs?

Establishing and maintaining a robust pharmacovigilance (PV) system requires the continuous monitoring and evaluation of process performance. Key Performance Indicators (KPIs) are essential tools to support this effort, providing measurable insights into how well process objectives are being achieved.



The starting point is the definition of a process objective, that is, what a particular process is intended to achieve. Depending on the context, this may include aspects such as performance, effectiveness, accuracy, consistency, adequacy, robustness, or compliance of a specific process. A KPI then determines how this objective is to be measured, typically through a quantitative or qualitative value that reflects the current "as-is condition" of the process.

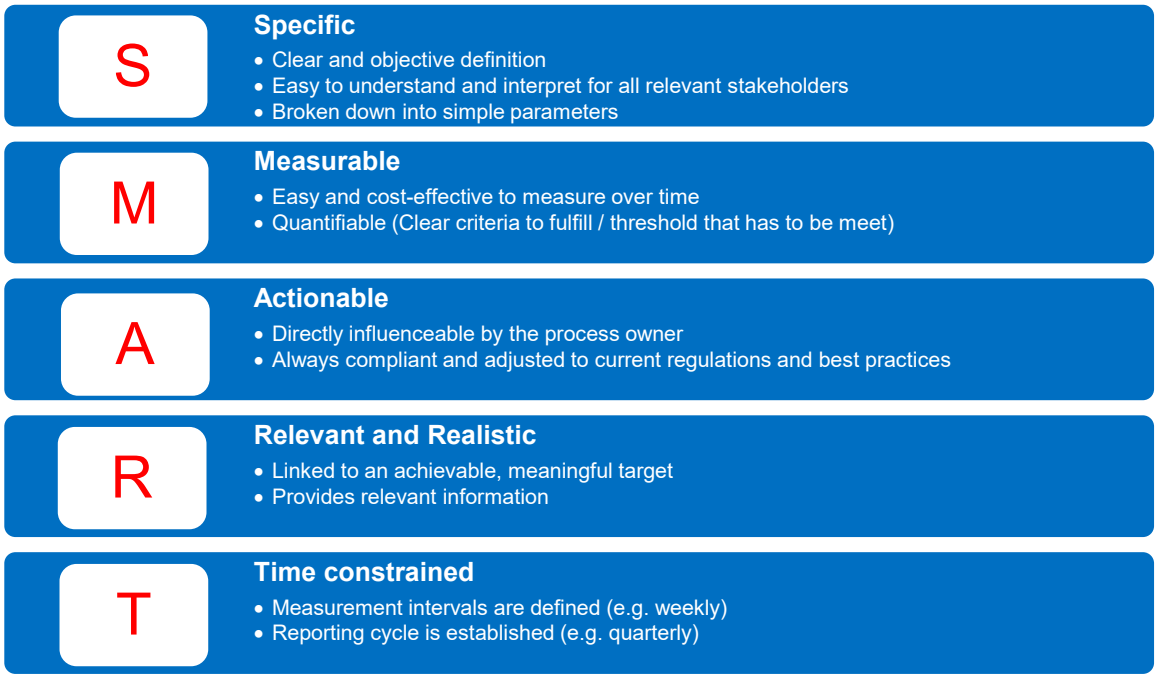
To make performance measurable and actionable, a target value is established. This represents the desired and realistically achievable level of performance and serves as the benchmark against which actual results are compared.

What are KPIs?

- They **monitor operational outputs of processes** help to **evaluate performance over time** and therefore, identify trends and detect deviations.
- They enable **process control** by triggering corrective or preventive actions (CAPAs) or process adjustments when targets are not met.
- They **support to overlook the quality control of the whole PV system**, through transparency for the Qualified Person for Pharmacovigilance (QPPV) and senior management.
- Set-up right and accurately documented, they **support regulatory compliance** and **ensure inspection readiness**.

1.2. What should KPIs be like?

To be truly effective, KPIs must meet certain quality criteria. They need to be clearly defined, measurable, and aligned with the strategic goals of the pharmacovigilance system. The following graphic illustrates the SMART principle that well-designed KPIs should fulfil to support meaningful performance monitoring and decision-making.



2. Why do we need KPIs in Pharmacovigilance?

KPIs are perfect tools to assess the performance of PV processes and therefore, of the whole PV system. Systematic performance monitoring is essential to maintain high process quality, ensure compliance, and ultimately safeguard patient safety. For this reason, a functioning and documented quality system in pharmacovigilance is not just recommended, it is a legal requirement.

2.1. Legal background

The legal requirement for quality systems was introduced by Directive 2010/84/EU (amending Directive 2001/83/EC) and Regulation (EU) No 1235/2010 (amending Regulation (EC) No 726/2004) to strengthen pharmacovigilance in the EU. The minimum requirements of these quality systems are set out in the Commission Implementing Regulation (EU) No 520/2012 on the performance of pharmacovigilance activities.

Although the GVP modules are not legally binding in themselves, they serve as recognised standards for implementing pharmacovigilance requirements. Following them is a well-established way to meet regulatory expectations. However, deviations from the GVP modules are possible, provided they are carefully justified, documented, and demonstrably compliant with applicable legislation. In the GVP framework, the modal verb “shall” indicates a legal requirement, while “should” denotes a non-binding recommendation or implementation guidance.

The recommendation to monitor and evaluate pharmacovigilance performance using KPIs is explicitly reflected in *GVP Module II - Pharmacovigilance System Master File*. Since *GVP Module I - Pharmacovigilance systems and their quality systems* provides the overarching framework of quality management in PV, it is useful to begin with the requirements set out in Section *I.B.9.1. Compliance management by marketing authorisation holders*. This section states that marketing authorisation holders shall implement defined procedures and processes as part of their quality system in order to ensure adequate compliance oversight.

GVP module I.B.9.1. Compliance management by marketing authorisation holders
For the purpose of compliance management, marketing authorisation holders shall have specific quality system procedures and processes in place in order to ensure the following:

- the continuous monitoring of pharmacovigilance data, the examination of options for risk minimisation and prevention and that appropriate measures are taken by the marketing authorisation holder [IR Art 11(1)(a)] (see Modules IX and XII);
- the scientific evaluation of all information on the risks of medicinal products as regards patients' or public health, in particular as regards adverse reactions in human beings arising from use of the product within or outside the terms of its marketing authorisation or associated with occupational exposure [IR Art 11(1)(b)] (see Modules VI, VII, VIII, IX);
- the submission of accurate and verifiable data on serious and non-serious adverse reactions to the competent authorities within the legally required time-limits [IR Art 11(1)(c)] (see Modules VI and IX);
- the quality, integrity and completeness of the information submitted on the risks of medicinal products, including processes to avoid duplicate submissions and to validate signals [IR Art 11(1)(d)] (see Modules V, VI, VII, VIII and IX);
- effective communication by the marketing authorisation holder with competent authorities, including communication on new or changed risks (see Module XII and XV), the pharmacovigilance system master file (see Module II), risk management systems (see Module V), risk minimisations measures (see Modules V and XVI), periodic safety update reports (see Module VII), corrective and preventive actions (see Modules II, III and IV) and post-authorisation safety studies (see Module VIII) [IR Art 11(1)(e];
- the update of product information by the marketing authorisation holder in the light of scientific knowledge [IR Art 11(1)(f)] (see Module XII);
- appropriate communication of relevant safety information to healthcare professionals and patients (see Module XII and XV) [IR Art 11(1)(g)].

By systematically using KPIs, organisations can ensure that their PV system remains transparent, responsive, and compliant, while also providing actionable insights for ongoing optimisation. Accordingly, section *II.B.4.6. PSMF section on pharmacovigilance system performance* recommends, using the word should, the ongoing monitoring of specific processes and their regulatory compliance via suitable KPIs. These indicators, alongside their results, must be listed in the PSMF.

GVP module II.B.4.6. PSMF section on pharmacovigilance system performance
The PSMF should contain evidence of the ongoing monitoring of performance of the pharmacovigilance system including compliance of the main outputs of pharmacovigilance. The PSMF should include a description of the monitoring methods applied and contain as a minimum:

- An explanation of how the correct reporting of ICSRs is assessed. In the annex, figures/graphs should be provided to show the timeliness of 15-day and 90-day reporting over the past year;
- A description of any metrics used to monitor the quality of submissions and performance of pharmacovigilance. This should include information provided by competent authorities regarding the quality of ICSR reporting, PSURs or other submissions;
- An overview of the timeliness of PSUR reporting to competent authorities in the EU (the annex should reflect the latest figures used by the marketing authorisation holder to assess compliance);
- An overview of the methods used to ensure timeliness of safety variation submissions compared to internal and competent authority deadlines, including the tracking of required safety variations that have been identified but not yet been submitted;
- Where applicable, an overview of adherence to risk management plan commitments, or other obligations or conditions of marketing authorisation(s) relevant to pharmacovigilance.

Targets for the performance of the pharmacovigilance system shall be described and explained. A list of performance indicators must be provided in the Annex to the PSMF [IR Art 3(6) and Art 9], alongside the results of (actual) performance measurements.

2.2. Prioritized KPIs

In line with the expectations set out in the GVP modules, some KPIs are considered mandatory and should be regularly monitored in any robust PV system. These KPIs reflect core regulatory requirements and have a direct influence on patient safety, compliance, and inspection readiness. Companies are encouraged to define and track additional KPIs, tailored to their specific processes, risk profile, or quality objectives. The following list summarises the prioritised KPIs that should be implemented in every effective PV system.

- **PSUR submissions**
  (e. g. timeliness, submission compliance, quality)
- **ICSR reporting and follow-up**
  (e.g. timeliness, quality)
- **Signal detection**
  (e.g. frequency, documentation, outcomes)
- **Safety variations and implementation**
  (e. g. timeliness, quality)
- **Risk management plan (RMP) commitments**
  (e.g. adherence)
- **Additional KPIs depending on the situation**
  (e.g. based on CAPAs or inspection findings)

Typical finding of BfArM & MHRA
Signal detection incl. missing timings, poor tracking and the delay in implementing safety variations

2.3. Quantitative and qualitative KPIs

Pharmacovigilance performance can be measured using both quantitative and qualitative KPIs. These two types complement each other and together provide a complete picture of system performance. A balanced set of both enables data-driven decision-making to support compliance, quality improvement and process robustness. For both categories, clearly defined evaluation criteria or target values must be established. Particularly for qualitative KPIs, a consistent and simple assessment process must be implemented to allow meaningful comparison over time, across systems, or between evaluators.

Quantitative KPIs	Qualitative KPIs
Countable, objectively measurable values with defined thresholds	Content-based assessments using defined criteria
• Submission compliance (e.g. ICSR, periodic reports) • Timelines compliance (e.g. reports, signal detection, safety variations) • ICSR follow-up rate • Trainings compliance	• Accuracy of translation (e.g. ICSR) • Quality of documents (e.g. ICSR, periodic reports) • Feedback from health authority assessments • Feedback on literature screening results

Best practices in KPI management

- **Combine both quantitative and qualitative KPIs** to assess system performance and to support ongoing improvement.
- **Apply KPIs consistently across internal teams and external partners** to align performance standards and monitor outsourced activities.
- **Automate wherever feasible** to reduce manual workload, ensure timely monitoring, improve result comparability and, therefore, increase reliability.

3. Setting up KPIs in Pharmacovigilance

A strong KPI begins with a clear understanding of the process, its goal, and its objectives. These objectives reflect what the organisation aims to achieve within the given process. KPIs translate the objectives into measurable terms.

To monitor process performance effectively, it is advisable to define one to five SMART KPIs per objective. Ideally, at least one KPI should relate to regulatory compliance, while others can focus on dimensions such as quality, efficiency, time, or cost.

To interpret KPI data, a target value is established. It represents the desired and realistically achievable level of performance and serves as the benchmark against which actual results are compared. Ideally, the target is defined collaboratively by the process owner (also responsible for its KPIs), a quality manager and the Qualified Person for Pharmacovigilance (QPPV). In addition or instead, multiple thresholds should be defined to facilitate interpretation: a critical threshold, a warning level, and an indicator for good performance.

Once KPIs are defined, they should become part of operational process management. They support ongoing monitoring, continuous improvement, and ensure that performance remains measurable, adaptable, and aligned with regulatory requirements. Regular reviews should be conducted to assess performance and define corrective actions if targets are not met. Operational objectives, targets, and KPIs should be reviewed and adjusted as needed.

Below are the key steps for setting up a KPI. To see case studies and get practical experience in setting up KPIs in pharmacovigilance, please visit our training course “Pharmacovigilance Key Performance Indicators”.

1 Define process goal	• Which process is being measured? • What is the goal the process aims to achieve? • When should the process goal be reached?
2 Identify potential data sources	• Which data is relevant to the goal? • Is the data easy and cost-effective to generate? • Should the data be compiled?
4 Select relevant data and define KPIs	• Which data relates to which strategic objective? • How does the KPI contribute to achieve goal/objective? • Define SMART KPIs, including purpose and target.
5 Establish data collection and management system	• Identify reliable and consistent data sources for each KPI • Define collection procedures: Where, how, when, by whom, and tools? • Define threshold levels.
6 Measure KPIs	• How often is the KPI measured? • Monitor over time.
7 Analyse, report, and present	• Define reporting cycle, including structure and format. • Define analysing cycle and corrective actions if targets aren’t met. • Review objectives, targets, and KPIs. Adjust if necessary.

4. Performance Analysis and KPI Dashboards

Once KPIs are defined and data is collected, the results must be analysed and presented in a way that is both meaningful and actionable. Proper performance analysis and effective visual presentation enable a deeper understanding of where adjustments may be necessary.

To ensure clarity and usability, KPI dashboards and reports should be designed so that they are immediately understandable, even without additional explanation. Each chart or graphic should include measurement dates, results, and the calculation method used for the KPI.

Visualisations should support the purpose of the analysis and be tailored to the addressed audience. For internal reporting, tools like Excel or PowerPoint are often sufficient. For more complex needs, advanced tools such as Tableau or Power BI can enhance clarity and interactivity. While graphical charts are ideal for review boards or management briefings, a structured table format is standard for documentation within the PSMF.

Objectives of KPI analysis and visualisation

- Identifying deviations from target achievement
- Conducting trend analyses to detect patterns over time
- Generating a comprehensive performance overview that highlights strengths, weaknesses, and areas for improvement

5. Conclusion and Seminar Invitation

Key Performance Indicators (KPIs) are the most suitable tools to ensure quality, compliance, and effectiveness of pharmacovigilance systems. They provide measurable insights into the performance of safety processes and help identify where adjustments may be necessary. Beyond fulfilling regulatory requirements, KPIs create transparency, support strategic planning and oversight, and drive continuous improvement.

To help you apply these concepts in practice, the FORUM Institut offers the seminar "Pharmacovigilance Key Performance Indicators – KPIs for a Robust PV System". In this interactive training, you will learn how to define meaningful KPIs, interpret results, and use performance data to support audits, collaborations, and outsourcing activities. Real-life examples and practical tools are provided to help you translate theory into daily application.

We hope this whitepaper has been informative. If you have any questions or would like more information about our online training course, please feel free to contact us.

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