

The role of pharmaceutical industry in Pharmacovigilance

30th Anniversary of National
Pharmacovigilance System
(INFARMED)

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The role of Pharma industry

Development of new or enhanced therapies, to fulfil unmet treatment and prevention needs

Bring those new therapies to market to improve patients' health and quality of life

Strict governance to conduct clinical research and product development activities

Conduct interactions with patients and healthcare professionals in accordance with ethical and legal principles

Compliance with legal and regulatory requirements worldwide

Pharmacovigilance in Pharma Industry

Pharmacovigilance is an essential component of Pharma Industry Activity

- Present in **all stages of product development**, throughout all marketing stages and until end of product's life cycle
- **Continuous monitoring of Benefit/risk profile**, regardless of product's life cycle stage
- All **new safety risks** are assessed on the need to take additional measures to minimise product associated risks
- **Robust Pharmacovigilance System** is needed to comply with regulatory requirements and to contribute to the protection of public health and promotion of effective use of medicines



Pharma industry activities requiring management of safety information

- Digital activities

- Social media (including social listening), websites, mobile applications
- Communication with consumers/HCPs about disease awareness
- Corporate/institutional awareness, clinical trial enrolment



- Market research activities

- Systematic collection and analysis of product or non-product specific data



- Promotional activities and other customer facing interactions with HCPs, in which safety information may be conveyed



Pharma industry activities requiring management of safety information

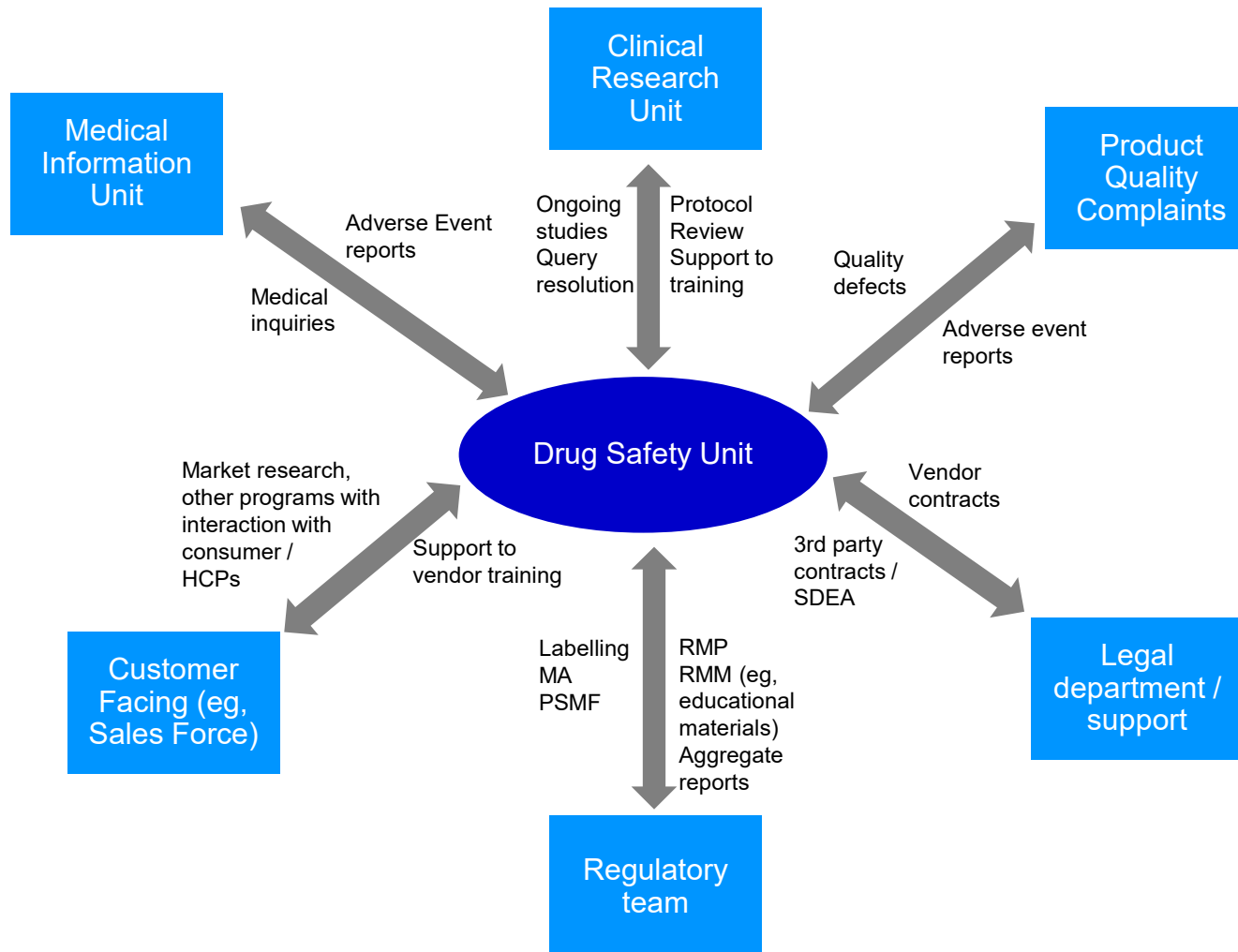
- Patient support programs
 - Disease self-management programs, patient Compliance/adherence programs, nurse programs (subject to local legislation)
- Clinical and non-Clinical studies
 - Clinical trials, non-interventional studies, other investigator initiated research, Expanded Access Programs (special access, compassionate use)
- Medical Information activities
- Management of Product Quality complaints



Pharma industry activities requiring management of safety information

For all activities in which safety information may be conveyed, a process must be in place to **identify and report** this information internally to the appropriate group (e.g, Pharmacovigilance Unit), within appropriate timeframes, to **allow proper regulatory reporting** and further safety analysis

Pharmacovigilance liason with other departments to ensure appropriate collection and management of safety information



Pharmacovigilance system

- The system to monitor the safety of authorized medicinal products and detect **any change to their benefit-risk balance** with the following quality objectives:
 - **Prevent harm** in humans from the use of medicinal products within or outside the terms of the marketing authorization or from occupational exposure
 - Comply with **legal requirements**
 - Promote the **safe and effective use** of the medicinal products
 - Contribute to the **protection of patients' and public health**



Stakeholders involved in Pharmacovigilance

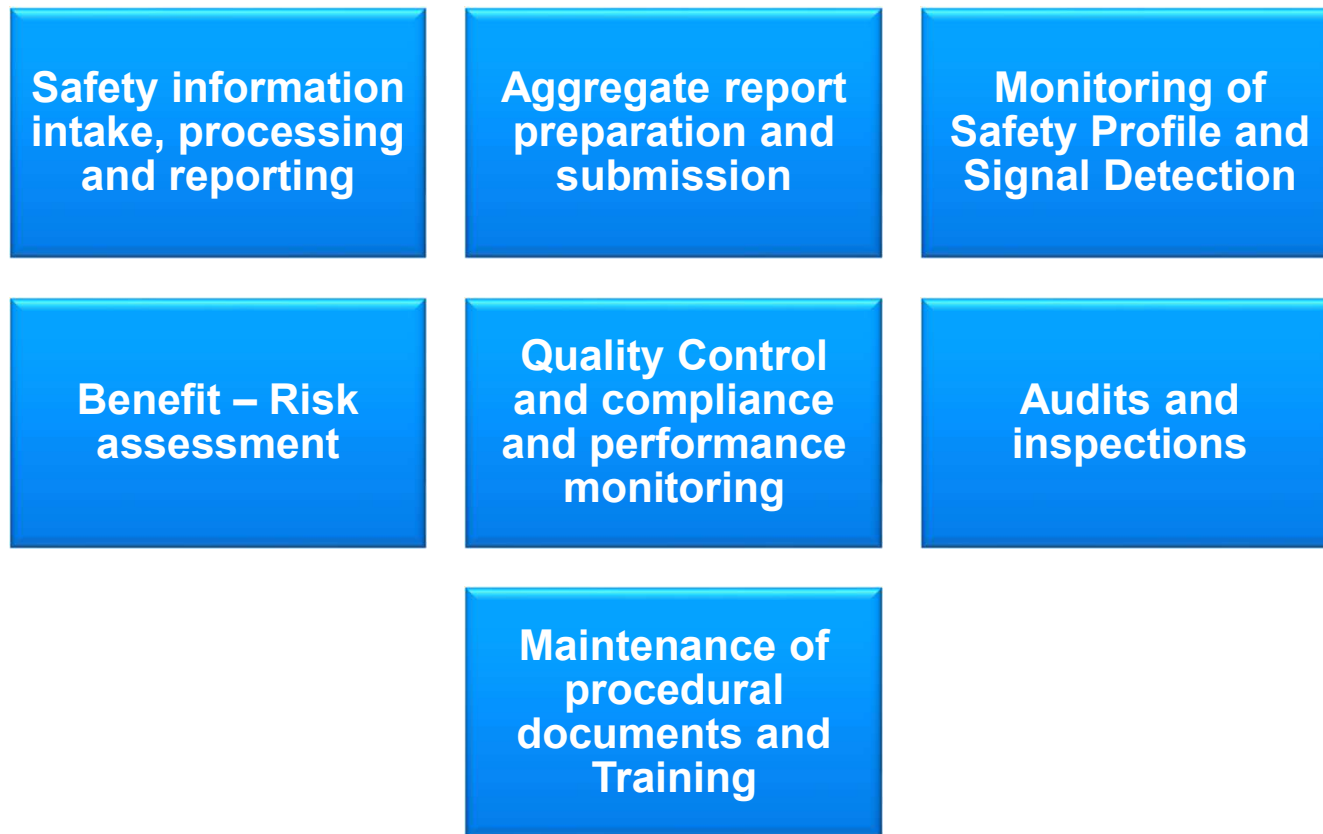


Pharmacovigilance activities

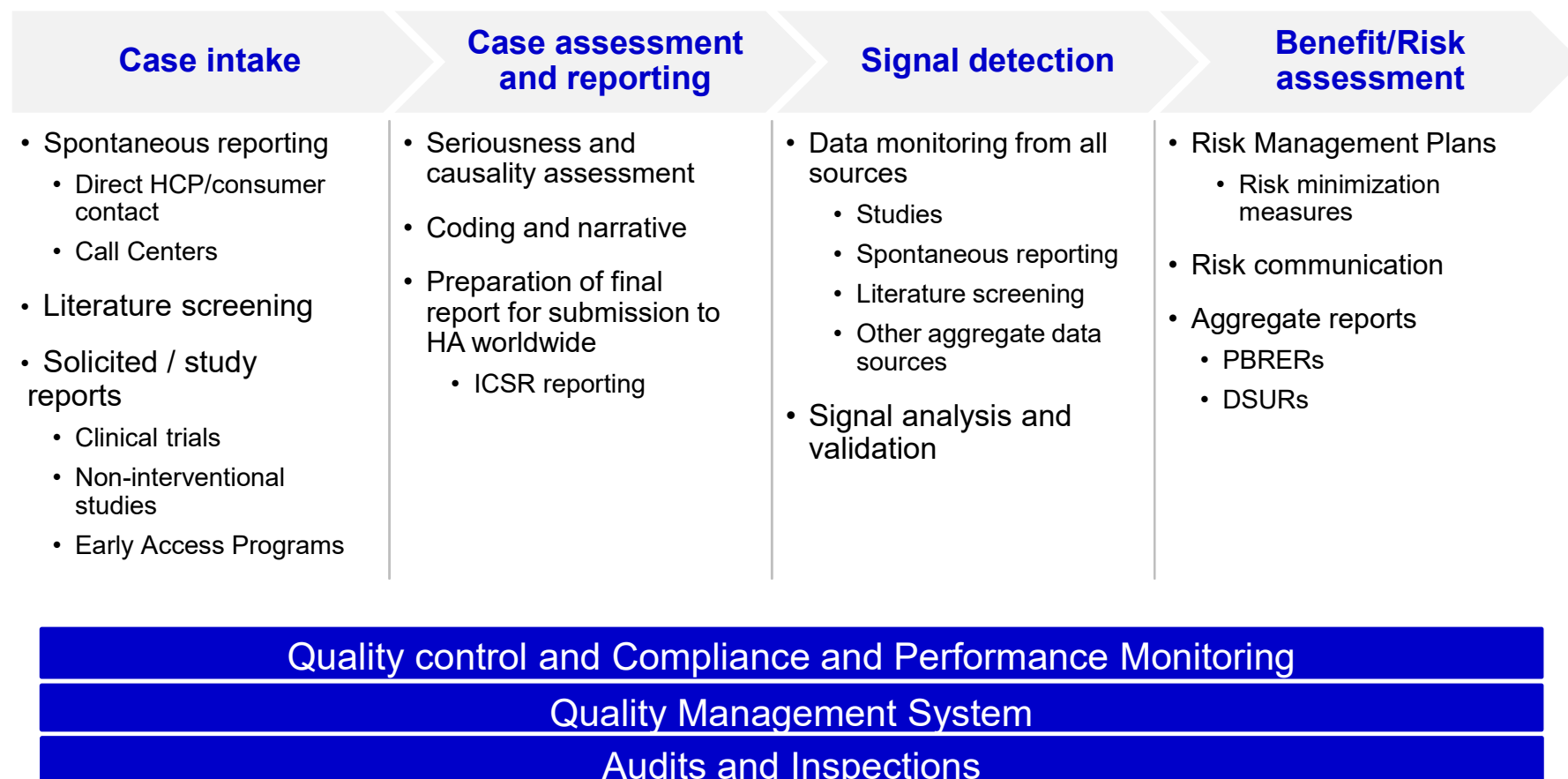
- Collecting and managing data on the safety of medicines
- Looking at the data to detect "signals" (any new or changing safety issue)
- Evaluating the data and making decisions with regard to safety issues
- Pro-active risk management to minimise any potential associated risks
- Acting to protect public health (including regulatory action)
- Communicating with and informing stakeholders and the public
- Audit of the outcomes and key processes involved.

Source: https://health.ec.europa.eu/medicinal-products/pharmacovigilance_en

Pharmacovigilance system components

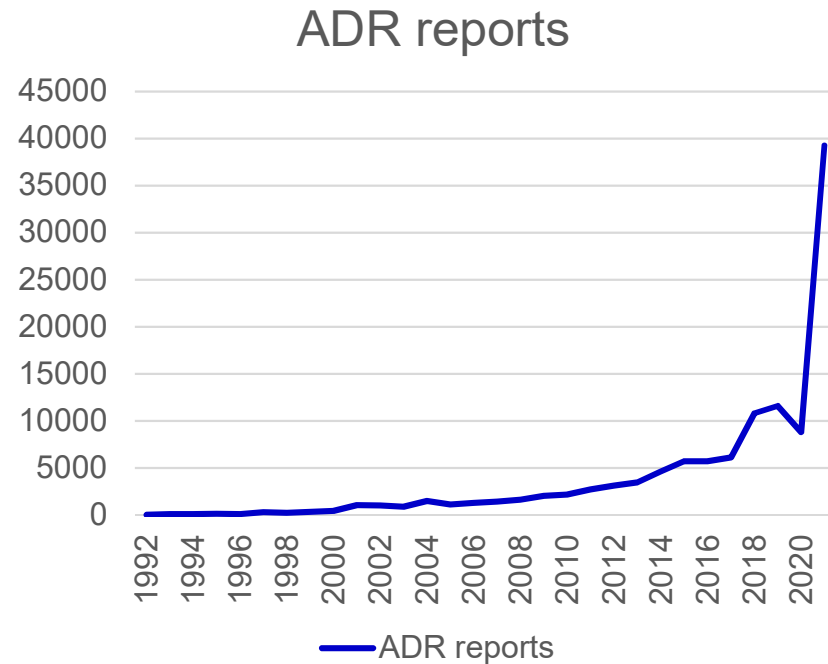


Pharmacovigilance system components



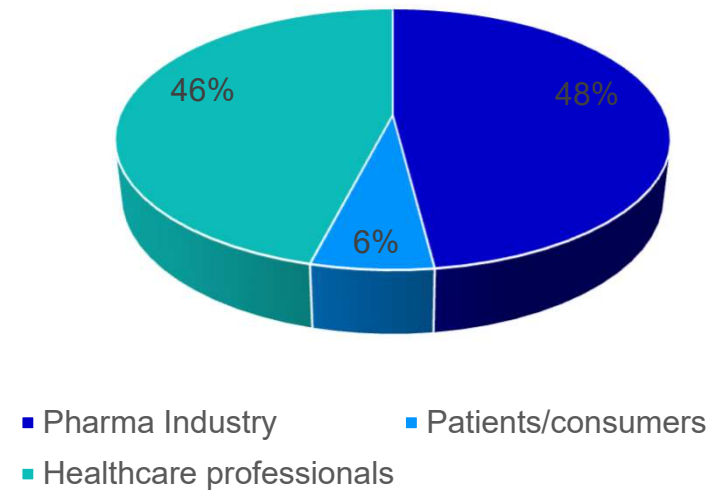
Pharma industry input to the National Pharmacovigilance System

Reports received per year



Reports received per source

ADR reports 1992-2021



Source: SNF – Relatório de Atividades 2021

Current challenges for Pharmacovigilance in Pharma Industry

Increasing volumes of safety information (leading to resourcing and costing issues)

Source of safety information heterogeneity, requiring different strategies for managing, depending on report type

Multilingual diversity and lay language versus medical language

Diverse and changing regulations

Large percentage of manual work

Source: *Database (Oxford)*, Volume 2022, , 2022, baac071, <https://doi.org/10.1093/database/baac071>

Technology challenges for Pharmacovigilance



Extracting ADRs from the scientific literature



Linking existing PV databases to incoming PV reports



Summarizing key information from PV-documents to facilitate review



Collecting relevant information to address ad hoc regulatory requests



Determine whether incoming ADRs require further study as safety signals

Source: *Database (Oxford)*, Volume 2022, , 2022, baac071, <https://doi.org/10.1093/database/baac071>

Present and future in safety information collection and management

Data mining
and ADR
extract
automation

Artificial
Intelligence (AI)

Machine
learning

Data mining:

The process of sorting through large data sets to identify patterns and relationships that can help solve business problems through data analysis

Artificial intelligence:

The simulation of human intelligence processes by machines, especially computer systems

Present and future in safety information collection and management - Data mining, AI and machine learning

Opportunities

- Reduce human error
- Reduced time to complete repetitive tasks
- Large increase on speed of data processing
- Improved analysis of large datasets
- Improved decision making
- Applicable to many PV activities (case intake, follow-up activities, signal detection...)

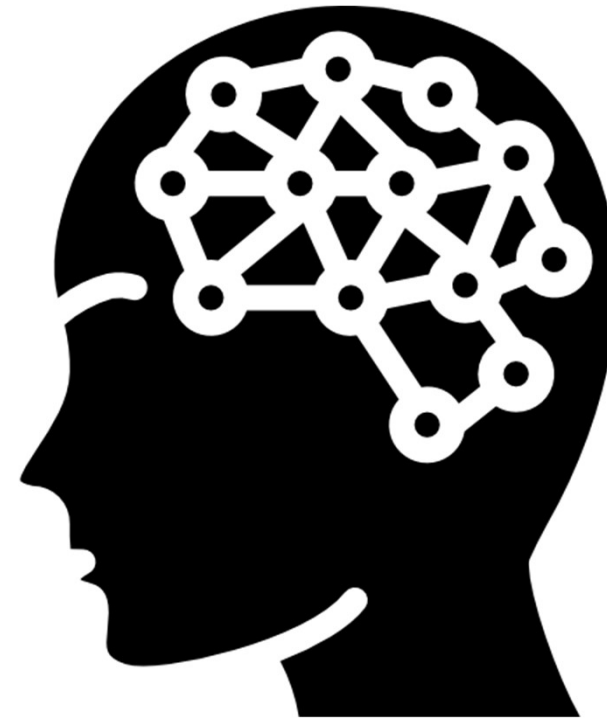
Challenges

- Lack of structured data to train the software to identify potential ADR
- Data quality
- Multilanguage and use of lay language (nonmedical terms)
- Possible privacy concerns

Sources: Database (Oxford), Volume 2022, , 2022, baac071, <https://doi.org/10.1093/database/baac071>;
Innovation in Pharmacovigilance: Use of Artificial Intelligence in Adverse Event Case Processing. Clin Pharmacol Ther. 2019 Apr;105(4):954-961. doi: 10.1002/cpt.1255

Present and future in Pharmacovigilance for Pharma Industry

- Automation is critical to reduce costs and complexities, process optimization and efficient resource allocation
- By using robotic automation, cognitive computing and AI technologies, companies can reduce effort required for case processing, allowing resources to focus on proactive identification, evaluation and minimization of risks
- Embracing advanced technology solutions and next generation automation as part of PV strategies is key to meet growing demands of the PV practices of the future, while ensuring compliance and quality
- Communication between all stakeholders (i.e., pharma companies and regulators) is essential throughout the process of implementing new technologies, to ensure all regulatory requirements are met





Thank You

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Breakthroughs that change patients' lives