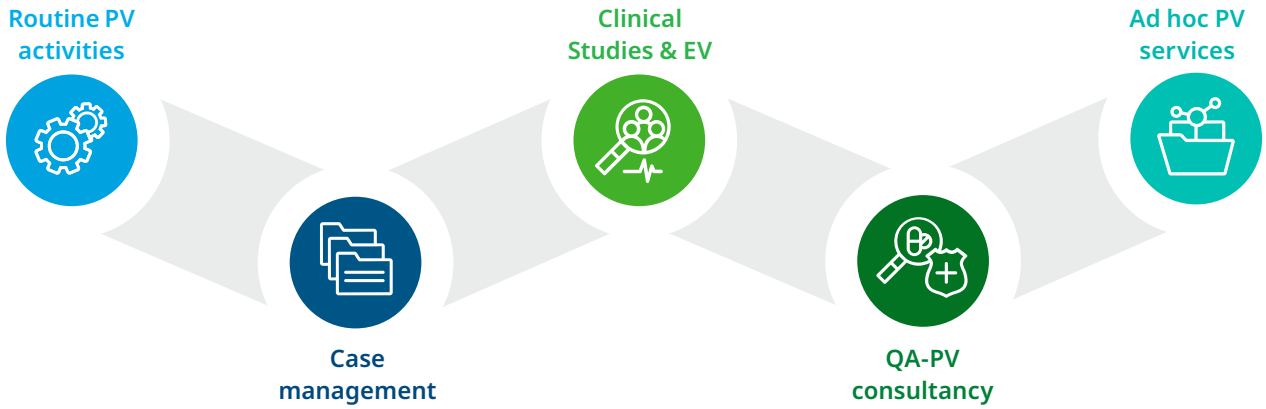
Pharmacovigilance Services

IQVIA is a partner capable of providing **advice** based on the specific needs of companies, who can offer, thanks to its experts, both specific and strategic **counseling** relating to the activities of **pharmacovigilance** (PV), in order to ensure solid and focused support to address the challenges of the pharmaceutical sector.

In this context, its crucial role is manifested through the careful management of the entire portfolio of Company products with consolidated expertise also in the use of related regulatory databases. Furthermore, IQVIA acts as a direct point of contact between Local/international authorities and the Local/Global Pharmacovigilance Department, ensuring continuity of activities and constant service coverage thanks to a dedicated team.

In particular, our solutions are aimed at providing complete support on drug safety:



Routine Pharmacovigilance Activities & Case Management

IQVIA offers comprehensive routine PV services that include **the assumption of responsibility** as **EU-QPPV**, single point of contact for EU competent authorities and the EMA, with 24-hour availability, including the possibility of a **local contact point**, a Deputy adequately trained on procedures and responsibilities, and a **back-up support** thus ensuring operational continuity in any scenario.

Among routine activities, IQVIA is committed to conduct **in-depth and accurate research of scientific and medical literature**, with a highly customizable service and guarantees an approach based on the best available evidences as important sources of identifiable safety information.

IQVIA also ensures that our customers operate in line with the latest industry regulations and guidelines, providing the **legislation screening & impact analysis** through an in-depth and customized assessment of the impact of laws and regulations on the safety and efficacy of products and allowing companies to make informed decisions.

An essential pillar for pharmaceutical companies is the **case management**. IQVIA guarantees effective and accurate management of **adverse reactions, adverse events, special situations** coming from different channels which may include, for example, but not limited to, **spontaneous cases, pre/post marketing studies, EAP, PSP, non-interventional studies, market research, Eudravigilance, non-profit clinical studies**. Our expertise allows us to develop targeted strategies to ensure a straight-forward proactive and competent management.

Relying on IQVIA's experience in the field of pharmacovigilance means guaranteeing support for an in-depth analysis of the data collected which allows, through the crucial activity of **signal detection**, a timely identification of signals of possible risks linked to the use of drugs and targeted interventions or regulatory actions.

Finally, IQVIA provides a support for **Eudravigilance (EV) activities** such as the activation and maintenance of the EV profile, the registration into the article 57 database and in the management of cases.

Clinical Trials & Eudravigilance

IQVIA offers complete and professional support for pharmacovigilance also in clinical trials through **protocol review** of the clinical study in order to improve the design of the study and the exchange of safety information of the product under investigation, the **revision of the e-CRF (Case Report Form)** and the **Informed Consent (ICs)**. Furthermore, IQVIA supports the sponsor in the development of **SAE (Serious Adverse Events)** forms and in the management of serious adverse events reported during the study.

IQVIA implements and forwards **line listings**, which contain information on adverse events reported during clinical trials, in a detailed and schematic manner. It also ensures the preparation of standardized periodical **DSURs (Development Safety Update Reports)** in

accordance with ICH guidelines and submission to the competent authorities via **CTIS**.

IQVIA's team of experts ensures the correct management and reporting of adverse events and **SUSARs (Suspected Unexpected Serious Adverse Reactions)** via the EV system, with a trusted deputy for **Eudravigilance**, ensuring the timely transmission of information to the competent authorities and the registration of the experimental product in **XEVMPD**.

Finally, IQVIA delivers **pharmacovigilance training during the investigators' meetings** ensuring a solid understanding of the main pharmacovigilance requirements applied to the clinical study.

Consultancy in PV-QA

IQVIA is responsible for ensuring the effectiveness and compliance of the processes used to monitor the safety of medicines. IQVIA QA experts take on the responsibility of leading **internal and external audits**, through systematic planning, from the preparation of the audit agenda to the delivery of the final report, and supports companies for inspection readiness activities and during **inspections and related follow-ups**.

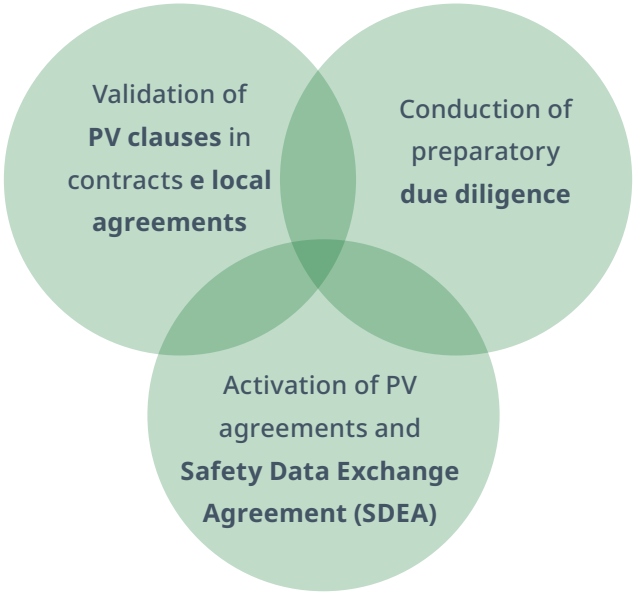
IQVIA supports in **creation and maintenance of Standard Operating Procedures (SOP)** specific for PV in order to guarantee adequate and regulatory compliant processes.

IQVIA services also include **writing and maintenance of the PSMF** with regular updating, constant monitoring and maintenance of **PV system** and **Pharmacovigilance Quality System**.

The **culture of compliance** must be promoted at all Company levels and departments. IQVIA ensures

that all Company processes and procedures comply with legislation, guidelines and internal standards. To continuously monitor the processes and performance of all activities, IQVIA supports in the periodic identification and recording of **KPIs (Key Performance Indicators)**, uniquely measurable variables without external judgements.

The quality system must also extend outside the MAH Company and involve all the stakeholders in a possible "chain" for the transmission of safety information. IQVIA can act as a point of reference between the Customer itself and third parties through:



AD HOC Pharmacovigilance Services

IQVIA offers ad hoc pharmacovigilance services including preparation of documents such as **Periodic Safety Update Reports (PSURs)** and **Pharmacovigilance Risk Assessment Report (PBRER)** in order to provide an assessment of the balance between risks and benefits of a medicinal product at defined intervals from authorization until submission, in accordance with current guidelines and legislation.

In order to ensure that all members of the Company are adequately trained on how to identify safety information and aware of the responsibilities and timing related to the reporting of adverse drug reactions (ADRs), IQVIA prepares and delivers the **pharmacovigilance training** to the Company population, including the field force and, where necessary, the Vendors.

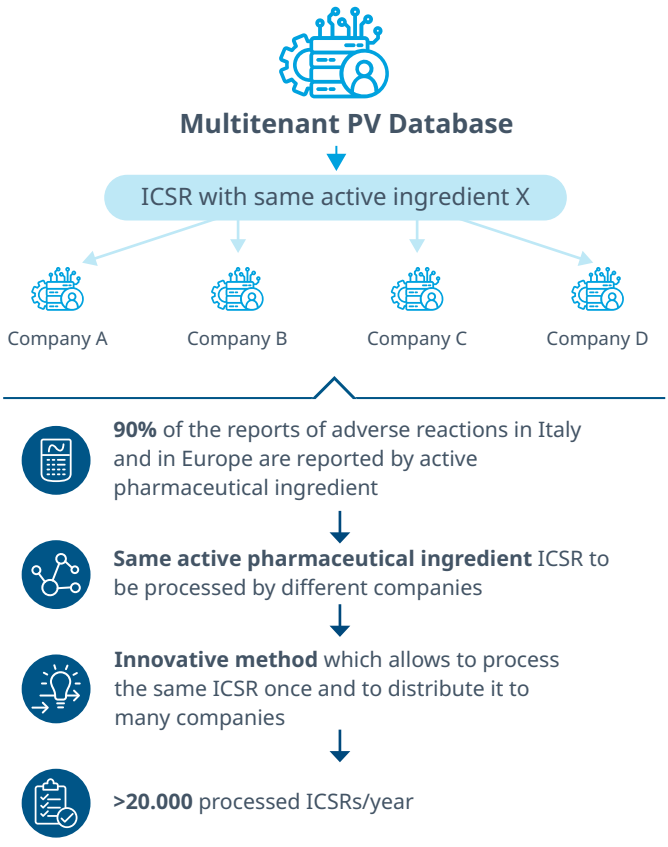
IQVIA takes care of **preparation and finalization of educational materials and DHPC (Direct healthcare professional communications)** for pharmaceutical companies, communicating with regulatory authorities for review and approval of materials; IQVIA also provides staff training on the same.

The **Risk Management Plan (RMP)**, as an essential tool to ensure the safety of medicines and minimize associated risks, it is one of the activities provided by IQVIA together with the identification of the safety profile, development of preventive and risk minimization measures, evaluation of the effectiveness of the measures and support in the management of post-authorization obligations (PASS and PAES).

Database for Generics Companies

Optimizing processes and using innovative methods allows management of Pharmacovigilance reports quickly and effectively.

IQVIA, thanks to its innovative **Multitenant Pharmacovigilance Database**, guarantees the simultaneous management of ICSRs (Individual Case Safety Reports) relating to the same active ingredient from multiple generics companies, processing over 20,000 cases per year, reducing costs and timescales.



The distinctive elements of the IQVIA Pharmacovigilance Team

IQVIA developed a Business Model to ensure a full and flexible support to our clients

Complexity — Cross-functional know-how within multiple fields of activities

Duration — Business continuity assured in every scenario

Urgency — Timely response to business needs

PV & Regulatory team allocated to the project

CONTACT US

Federica Santagostino

Regulatory & PhV Engagement Manager IQVIA

federica.santagostino@iqvia.com

IQVIA Solutions Italy S.r.l.

Via Fabio Filzi, 29 | 20124 – Milano – Italy

iqvia.com