# Your full-scope pharmacovigilance provider

## Full-service provider with strong expertise in global pharmacovigilance management

In 2007, SocraMetrics was founded from SocraTec R&D's biometrical department, with strong focus on IT and clinical data management. Since 2014 , SocraTec R&D and SocraMetrics have a long-term collaboration with a pharmacovigilance team based in Berlin, Germany. In summer 2023, the pharmacovigilance team finally joined SocraMetrics and opened up our pharmacovigilance service offering.

Global PV System

We can offer you a one-stop shop in regard to pharmacovigilance services and consulting. Our highly experienced pharmacovigilance team does not only manage the set-up and maintenance of the global pharmacovigilance system for sponsors of clinical trials and marketing authorisation holders (MAHs)/ applicants but also provides the legally required responsible persons for pharmacovigilance, such as:

- EU-QPPV
- UK-QPPV
- Graduated Plan Officer (Stufenplanbeauftragter)
- Safety Officer for medical devices
- Drug Safety Officer for clinical trials

Hereby, SocraMetrics may act as your pharmacovigilance department or provide consultancy on certain topics. We will manage your projects globally, supported by our well-established network of contract partners.

SocraMetrics will support you from the development phase and throughout the entire lifecycle of the medicinal product.

Excellence and Quality

The excellence of our team as well as our outstanding quality management system was proven by various inspections of competent authorities.

# Pharmacovigilance for clinical trials

SocraMetrics provides the full scope pharmacovigilance services for sponsors of clinical trials on a worldwide level, handling all phases (I – IV). We have broad experience with multicentric clinical trials which include various parties and extraordinary setups. We will guide and support you throughout any safety challenge.

Worldwide PV
Management of Early and
Late Phase Clinical Trials

Our offered services include:

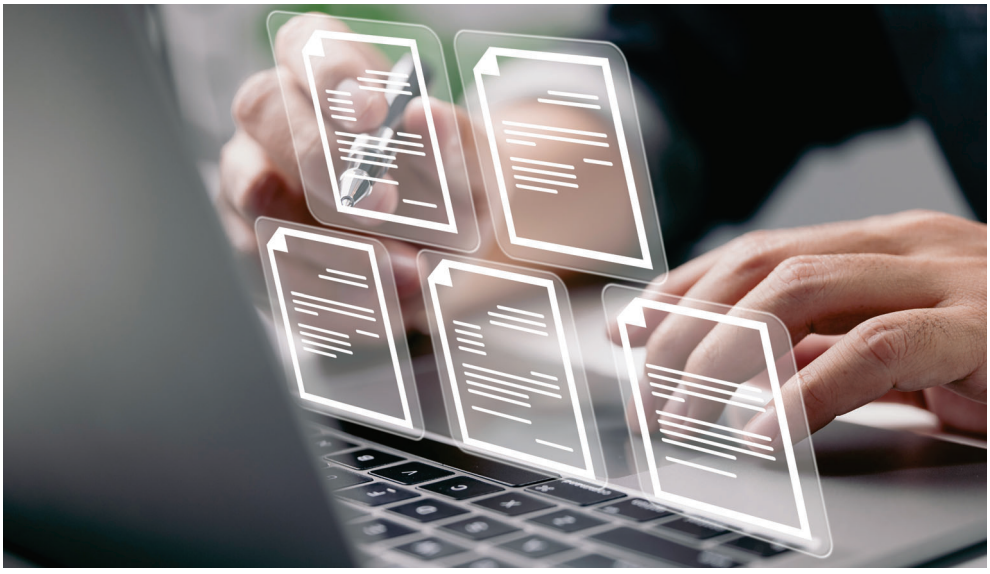
- Consultancy on PV topics incl. communication with authorities
- Set-up and maintenance of the global drug safety system
- Global drug safety project management incl. Drug Safety Officer
- Signal management
- Drug safety quality system support (set-up and maintenance)
- Safety Management Plan (SMP)
- Periodic reports including development safety update reports (DSURs)
- Case processing and reporting (SAEs, SUSARs)
- GCP trainings
- PV input to a variety of mandatory medical writing documents such as protocols and IB's
- Literature search
- Set-up and maintenance of product databases (e.g. XEVMPD)
- Audit and inspection support
- Setup and maintenance of safety database, e.g. ARGUS, ArisG
- Support in regard to independent drug safety monitoring board meetings

Our services for clinical trials are perfectly complemented by the Data Management and EDC teams of SocraMetrics, whenever needed.

Pharmacovigilance, Data
Management and EDC

# Pharmacovigilance for applicants and MAHs

SocraMetrics provides the full scope pharmacovigilance services for applicants of marketing authorisations and marketing authorisation holders and will set-up and maintain a compliant global pharmacovigilance system. We handle your worldwide project management including vendor and contract management.



Our in-house personnel covers the regions EEA and CH and we collaborate with a well-established network of contract partners to cover other regions.

Our offered services include:

- Provision of EU-QPPV, UK-QPPV, German Graduated Plan Officer, local responsible person for PV in AT and CH
- Consultancy in the context of marketing authorisation procedures
- Worldwide project management incl. vendor and contract management
- Signal management
- Pharmacovigilance quality system set-up and maintenance
- Pharmacovigilance system master file (EU and UK PSMF)
- Risk management incl. risk management plans (RMPs)
- Periodic reports, e.g. periodic safety update reports (PSURs)
- Management of cases and pharmaceutical-technical risks/complaints
- Literature search in English and German
- Giving PV trainings including inspection-readiness trainings
- Set-up and maintenance of product database (XEVMPD)
- Audits and inspection support
- Setup and maintenance of safety database, e.g. ARGUS, ArisG

# Why us?

Our well-established and highly experienced team seeks the close contact to you as the client and supports you in all aspects of pharmacovigilance and vigilance with tailored solutions and processes. We really care about your needs, your products and your success while ensuring full regulatory compliance.

Interested ? Let's have a conversation.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