

Pharmacovigilance & Medical Writing

Everything around your clinical trial – and beyond

SocraTec R&D and SocraMetrics offer you the full range of customised medical writing solutions and full-scope pharmacovigilance services for clinical trial sponsors, marketing authorisation holders and applicants.

Our services span the entire lifecycle of your product from early clinical development to marketing authorisation and beyond. We provide pharmacovigilance services and clear, concise, and regulatory-compliant medical and scientific documents.

Pharmacovigilance Services

Our highly experienced pharmacovigilance team does not only manage the set-up and maintenance of the global pharmacovigilance system but also provides the legally required responsible persons for pharmacovigilance, such as:

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

<https://socrametrics.com/pharmacovigilance>

Medical Writing Services

Our medical writing experts provide you with ALL documents needed for each stage of your clinical development

- **Clinical trial documents**
e.g. clinical study protocols and reports, investigator's brochures, lay summaries
- **Regulatory documents**
for marketing authorisation applications (EU and USA)
- **Medical communications documents**
e.g. conference abstracts/posters, publications, brochures

<https://socratec-pharma.de/services/medical-writing>

Inspection-ready quality standards



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



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Pharmacovigilance & Medical Writers Team



Embedded in full-service CRO



Consultancy expertise from 25+ years



Global project management



Close client collaboration



Tailored solutions and processes

Why we are unique

We work in a dedicated team of biopharmaceutical, clinical-pharmacological, statistical and regulatory specialists. SocraTec's services for clinical trials are perfectly complemented by the Data Management and EDC teams of SocraMetrics.

We manage your projects globally, supported by our well-established network of contract partners.

We focus on close client collaboration, offering tailored solutions and processes to ensure excellent service at every stage of your product development.