



Pharmacovigilance

Be sure to comply with current legislation.

Doubt is not an option. With LINK Medical, you can be sure that everything is covered. We provide pharmacovigilance services regarding medicinal products for human and veterinary use as well as for medical devices.

Let our highly experienced and dedicated team deliver an individual solution that suits your pharmacovigilance system. Perfectly.

At LINK Medical, you will find all the expertise you need. Our specialized consultants can guide you through the process and implement the Good Vigilance Practice for medicinal products for human use. You can also get assistance and guidance on vigilance practice for medicinal products for veterinary use and medical devices.

Outsourcing

You will always receive the solution which is best tailored to your purposes. You can choose to insource our consultants to your facility or outsource your assignment to be executed by our in-house resources.

- Full pharmacovigilance services
- Act as your external pharmacovigilance department
- Back up during holidays, sick leave, etc.

Pharmacovigilance system

Writing and maintenance of the Pharmacovigilance System Master File (PSMF).

This can include:

- Risk Management Plan (RMP)
- Standard Operating Procedures (SOPs)
- Signal detection and evaluation

Pharmacovigilance services

Get the full advantage of our experience in national and international drug safety reporting in clinical trials and post-marketing. You can count on us all the way from receipt of initial data to regulatory reporting. Our safety officers are certified users of the EudraVigilance web-based reporting tool (EVWEB).

Our services include:

- Spontaneous and periodic reporting of adverse events
- Electronic reporting (EudraVigilance, EudraVigilance Veterinary)
- Registration of product information in XEVMPD
- Literature searches - local and worldwide
- Medical coding (MedDRA, VedDRA)
- Medical evaluations

Other services

- Quality assurance
- Audits
- Training

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