



Bibliographic Search

Electronic search of adverse events in databases of international and national medical literature.

Shipment of abstracts or articles in full text to the customer electronically .

Search for updated magazines.



Pharmacovigilance in clinical research

Deploying and monitoring of Pharmacovigilance programs in clinical research, according to the DRC 39.

Structuring of the area, development of workflow and procedures, integrated design with software for management of Pharmacovigilance in clinical research training of teams of managers and monitors.

Pharmacovigilance / Cosmetovigilance / Tecnovigilance

- Deploying and monitoring of Pharmacovigilance, Cosmetovigilance and Tecnovigilance programs.
- Optimizing processes to capture, record, monitoring and analysis of Adverse Event Reports.
- Interface with the Customer Service, Sales Force, Quality Systems, Regulatory Affairs, Legal Department, etc.
- Development of informational materials, computerized reports, follow up and reporting.
- Advice for setting up workflow for routine pharmacovigilance processes (integrated project with computerised system).
- ➔ Drawing up documents in Pharmacovigilance:
- ➔ Operational procedures DDSF (descriptive document of the pharmacovigilance system)
- ➔ Periodic report of Pharmacovigilance/Risk Minimization Plan
- ➔ Periodic electronic search with adverse events reporting Causality assessment performed by a physician experienced in the Pharmacovigilance area.
- Auto inspection, issuance of conclusive report, treatment of non-compliance, action plan for improvements.

Trainings In Company

The trainings are customized according to the needs of each client.

Check out the main themes of training:

- Aspects of current legislation: RDC 04/2009 and 5/2010 CVS.
- Interface areas with Pharmacovigilance: SAC, Quality Systems, Regulatory Affairs, Legal Department, Sales Force.
- Behavioral and technical aspects involved in the capture of adverse events.
- Documentation in pharmacovigilance.
- Signal detection.
- Risk management.
- Regulatory actions.
- Practical exercises for the notification SNVS

