

Safety surveillances as part of risk management

Post approval risk management plays an important role for regulatory agencies to increase the safe use of approved medical products. FDA as well as EMEA understands the need to give the public access to beneficial medical product as long as residual risk is properly managed.

One effective method for active risk management is the use of a Post Approval Safety Surveillance (PASS) also addressed as Large Simple Safety Study (LSSS). They allow the collection of additional safety information under standard practice condition. To extend the information base already available from clinical trials phase I to III, phase IV trials or registries usually involve a high number of patients and run over a longer period of time. Efficient data collection methods are a prerequisite in order to handle the trial cost effectively.

Business Case and Issues

Typical reasons to carry out post approval safety surveillances are:

- Collection of additional safety information to confirm and refine safety profile
- Products where rare but severe adverse reactions cannot be ruled out
- Monitoring of the drug as used in real life (day to day medical practice)
- Prevention of use in contra-indication situation (e.g. use during pregnancy, off-label use, comedication)
- Products for which trust of authorities, prescribers and patients has to be established, enhanced or re-established.
- Biogenerics

A phase IV study / surveillance can fulfil the following objectives:

- Increase of risk awareness of the prescriber (e.g. liver values, immunogenicity)
- Increase compliance with monitoring requirements as per Specific Product Characteristics (SPC)
- Early detection of safety signals
- Motivate the prescriber to report adverse events to underline the safety profile

Many Post Marketing Safety Surveillances can be set up as non-interventional surveillances and therefore do not fall under the European Clinical Trial Directive (2001/20/EC). This allows for more freedom in clinical trial design, increasing acceptance by the prescribers and facilitating operation by the sponsor. Good EDC technology will allow maintain data quality.



Risk management programs should be drafted before filing a new drug for regulatory approval. A good risk management program will accelerate the approval process. Additionally, it gives a competitive advantage by reducing prescribers' safety concerns and increasing the visibility of the product.

Capabilities and Experiences of IBR AG

IBR AG implemented several post marketing surveillances using Electronic Data Capture (EDC) for international pharmaceutical industry. Two of the surveillances were developed to fulfil obligation of EMEA to increase compliance to the SPC and to collect additional safety data as part of the post marketing risk management program.

IBR AG is following developments in risk management and pharmacovigilance closely and is able to support pharmaceutical companies in other aspects of risk management such as reconciliation of adverse events with the drug safety database or set up of reports to detect safety signals.

Services

You may expect from us:

- Consulting in risk management, with particular emphasis on data management technology
- Planning and management of your safety surveillance project
- Evaluation of technology and vendor appropriate for your special needs
- Vendor and budget management
- Consulting in technical and regulatory aspects relevant to EDC
- Concept to assure validation of hardware and software
- Hands on day to day project support

Benefits of partnering with IBR AG

Working with IBR AG lets you take advantage of experience gained over years with a multitude of successful projects in the area of Electronic Data Capture and Safety Surveillances. You will work with professionals with many years of experience in the life science industry