Case Study

PROPHARMA GROUP™

The Challenge of Risk Assessment of Potential Medication Errors to Regulatory Authorities in Multiple Territories

This case study describes how ProPharma Group supported the implementation of risk assessment as part of the regulatory approval process for a pharmaceutical product that has the potential for medication errors.

Background

A pharmaceutical manufacturer is required to hold a license for any pharmaceutical product that has the potential for medication errors upon administration. As part of the approval process for that product in a given territory, potential medication errors must to be accounted for. Regulatory agencies across different territories have different reporting requirements, as well as varying definitions of what constitutes a medication error.

The Challenge

Safety data for clinical studies should be accurately and consistently captured to ensure that the data is defendable upon presentation to regulatory authorities and the medical-scientific community. To ensure the defend-ability of the data, clear definitions must be constructed surrounding the categorization of adverse events and conventions developed on how this information will be captured in the safety database. In addition to these measures, program oversight and close collaboration with the sponsor is essential, to plan for the output required at study closure for the safety analyses.

The Approach

ProPharma Group's team performed an initial, in-depth review of regulatory guidance, regulatory guidelines, and procedural guidelines for best practices in multiple territories. Then, medical dictionary coding and product labeling were reviewed, as were all databased adverse event cases for that product to identify potential/documented administration errors. Round table discussions were held with the pharmaceutical manufacturer to obtain their insight, as well as to incorporate feedback received from the approving regulatory agency surrounding the draft medication error form.

The Outcome

With the support of ProPharma Group, a medication error form, applicable to all approving regulatory agencies, was created to document the medication error. This included: the classification, stage, and setting of the medication error; any contributing factors; a risk assessment, including potential quality defects or failure of the product, and any trends found within the safety database, and whether harm occurred to the patient/exposed party as a result of the error; a risk-based investigation plan; a root cause analysis; and a closure statement, including remedial, corrective, and preventative actions. Upon receipt of any potential medication error, this form is filled out in its entirety and approved by both the pharmacovigilance provider and the pharmaceutical manufacturer.

Learn how ProPharma Group can build a clinical safety solution to fit your needs. Contact us today at ProPharmaGroup.com/contact.