Sophisticated Literature Automation Module to cope up with global scientific literature surveillance

Abstract

Literature surveillance is an incessant activity for Good pharmacovigilance practices. If this process is technology-aided in conjunction with the automated search hits from global medical literature, the resources can work efficiently in early safety risk detection after reviewing and categorizing literature of interest for safety reporting.

Sarjen Systems Pvt. Ltd.

ISO 9001:2008 certified company

About Sarjen

For more than a decade and a half now, Sarjen Systems Pvt. Ltd. is a sought after choice for Technology solutions in the field of Drug Safety, Clinical Trials management, e-Dossier submissions and SAE management for Ethics committees. We customize our solutions to adapt to the regulatory submission requirements and suit our client's prerequisites or a way forward, provide them with feasible alternatives. We cater to knowledge and current regulations in the field of regulatory, pharmacovigilance and healthcare along with prompt, advanced solutions to e-reporting. Sarjen Systems is into consulting and providing e-tools which are not only user friendly but also cost effective. We believe in having a loyal clientele base to whom we provide dedicated resources and domain expertise so that e-submissions in collaboration with our technology solutions will be a prime privilege.

See what industry leaders are saying about us.

PvNET - the advanced Adverse Event Reporting solution has successfully cleared MHRA, US FDA and different European authorities regulatory inspections and also Third party audits

For more details on our pharmacovigilance services and to help us facilitate you, please visit www.pvnet.in

Client Introduction

The client is a reputed, established Contract Research Organization (CRO) having global presence and carrying out early phase trials, Phase II-IV clinical trials, bioequivalence and bioanalytical studies and product safety reporting.

Requirement/Challenge

Literature review is the integral activity for pharmacovigilance.

The Client's pharmacovigilance team was reviewing the literature articles manually in MS Word document and isolating it for further review or rejection. Problems occurred when same articles re-entered the literature process cycle and only after partial or complete review of the article again would the professional realize that it is an already screened article.
There was no valid method to address the articles that were already rejected by the medical reviewers. The non-selected literature articles would enter the loop unnecessary reiterating the whole process.

Troubleshooting

Sarjen systems clearly understood the challenge and provided a flexible literature automation module (LAM) in PvNET, comprehensive adverse event reporting solution. Literature monitoring through literature automation module was faster, validated and an audit trail was maintained throughout all the steps.

The articles were categorized as selected, rejected or article of interest and filtered accordingly. This helps data to be retrieved speedily during aggregate report preparation, signal detection activity or in case of any regulatory authority request for specific product and period.

For selected literature articles categorized as ICSRs, the case could be automatically created in PvNET. This resolved the problem at different safety data management user-cadres and hence no further discrepancies were generated.

Client Process Improvement

➢ Substantial time of searching literature and data entry into the system was saved. Safety literature articles that were already dealt with were segregated

➢ The scientific literature database had multiple-embedded options for easy search, archives of literature searches, summary of project- and client-specific literature details etc.

➢ The implementation of LAM caused improved process efficiency in addition to automated literature case entry

Contact Us

Corporate Communication

corp.comm@sarjen.com

Websites:

Company Website www.sarjen.com

Adverse Event Reporting Tool www.pvnet.in

Clinical Trail Management www.biznet-ctm.in

Dossier Project Tracking and Submission www.knowledgenet.in

Quality Management Systems www.qedge.co.in

Social Media

Get the latest news, insights, and ideas from Drug Safety and Pharmacovigilance

Pharmacovigilance updates on LinkedIn

Get latest from technology updates, products, services, webinars and many more details from social media.