AUTOMATED ELECTRONIC SAFETY FORMATS TO COMPLY WITH GROWING REGULATORY NORMS

ABSTRACT

Every day Pharmaceutical and Biotechnology companies face safety reporting challenges as new regulations gain momentum. Current case study is about achieving a Regulatory milestone (E2B (R2) compliant format) crucial for pharmacovigilance submissions to Regulatory Agencies

Sarjen Systems Pvt. Ltd.
ISO 9001:2008 certified company

PvNET
values patient safety

ABOUT SARJEN

For more than a decade and a half now, Sarjen Systems Private Limited 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 well-known Clinical Research Organization having global presence of 14+ years in carrying out early phase trials, bioequivalence and bioanalytical studies and pharmacovigilance. Client has remarkable presence in the clinical research industry.

Need for Regulatory compliance

The client wanted to match the constantly growing Regulatory expectations. They needed system-automated XML formats for import of a safety report from Regulatory authority as well as export of Individual case safety reports (ICSRs) electronically to EMA/FDA and other regulatory authorities, accepting safety data only in structured XML formats.

Troubleshooting

PvNET, Sarjen's comprehensive Adverse Event reporting solution, very well catered to this Regulatory requirement of import and export of safety data in XML formats, precisely complying to the guidance on technical specifications for data elements.

The format was compatible for database to database transmission thus ensuring there were no failures encountered while transferring the files.

Client Process Improvement

System-generated XML formats ensured that the safety data could be transmitted to Regulatory authority in their accepted format (ICH E2B and 21CFR Part 11 compliant).

The bonus point was auto-population of safety data from imported XML files in the respective data fields leaving the advance data entry personnel to only review the data entered. This minimized the possibility of trivial data entry errors while performing basic data entry.

Contact Us

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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

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