PvNET
values patient safety

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‘Systematized’ approach for expedited pharmacovigilance submission in varied countries

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

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www.pvnet.in

Client introduction

The Company is a renowned clinical and pharmacovigilance (PV) service provider with history of unparalleled regulatory compliance since 100+ years. They are involved in contract manufacturing on a large-scale as well as providing clinical trial/BABE and PV services as a well-known service provider. The company has had several million dollar expansion in commercial scale manufacturing and quality control of pharmaceutical products.

Expedited (ICSRs) Submission timelines

In an Industry with ethical and regulatory obligations to accomplish and with the expectations of far-sighted Sponsors competing to ensure benchmark practices every day, it is indeed impossible to afford failure in submitting Individual Case Safety Reports (ICSRs) within governed timelines. A deviation is likely to be filed with delay in these case submissions.

For a company of gigantic size having hundreds of pharmaceutical products manufacturing and marketing, it is but a challenge to identify a rare reportable ICSR that might be over-sighted by user.

Mechanism to avert expedited ICSRs submission delay

Undoubtedly, company had its own procedures to assure that there are no delays in stipulated submission timelines. However, PvNET recognizes the criticality of managing varied country-wise submissions and thus, has an inbuilt mechanism to alert the submission users of the expedited cases and where (submission country) they should be submitted based on reporting criteria.

System monitoring and tracking of expedited submissions in countries

Automated provision set for the delegated PV team to:

- Figure out the number of expedited ICSRs and also non-serious ICSRs
- Due submission regions/countries where ICSR must be reported to applicable regulatory
- Current (workflow) status of thousands of expedited ICSRs in database
- Alerting teams for cases nearing its reporting time frame and yet in early workflow stages

Key regulatory and user gains

- Intricacy of different regional reporting rules is simplified and automated in database
- Direct outcome of countries where the expedited ICSRs should be submitted
- Flexible configurations possible for non-serious ICSR submissions

- Nil deviations & audit/inspection findings as system alerts user on submission criteria
- Delay as per reporting time frames prevented due to human omission
- User is spared from laborious efforts to remember/track ample submission countries where cases are due for expedited (usually 15-day) submission compliances
- Much time spent in determining eligibility as per product's Marketing authorization details can be utilized in quality tasks and productivity escalation

The robust PvNET safety database is adaptable to incorporate requirements of clients for product safety profile management, including large-scale manufacturers, manufacturing and marketing medicinal products worldwide and willing to have in-house drug (product) safety set up.

Contact Us

Corporate Communication: corp.comm@sarjen.com

Other websites:

Clinical Trial 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 updates on LinkedIn