PvNET
values patient safety

2017

DIFFERENT APPROACHES TO SUBMISSION OF ICSRS AND TRACKING SUBMISSION ELIGIBILITY

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Background

Pharmacovigilance is a versatile industry where there is a constant, ever growing need to identify the key areas of compliance and make sure that team is well-aware and trained to achieve core compliance. Diverse Clients of Sarjen's PV solution also wanted to assure adherence to such areas; one of them being Submission tracking system. There were certain concerns to address for submission of reports and automate the process using a robust system.

Client's Concerns

The Clients had mainly following Submission concerns:

- Needed a submission system where different submissions are tracked
- Needed a system to update users on eligible countries for submission
- Needed a system to submit ICSR reports in different regions as well as to EVHUMAN
- Wanted to upload submission dates and Acknowledgement files at once for multiple submissions

Sarjen's Challenge

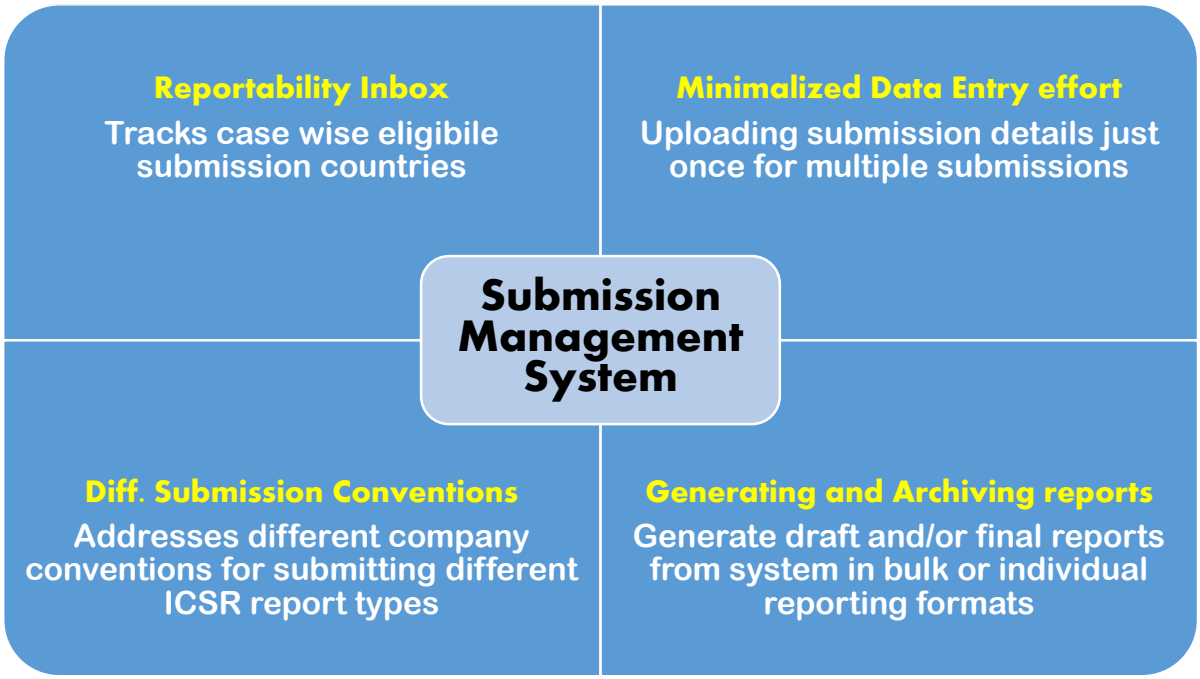
Overall, Clients had an expectation of a flexible yet user convenient submissions management system to allow for tracking, reporting and managing submission files.

- Complying to different submission conventions of various companies
- EVHUMAN submissions and minimalizing data entry effort of Submission user
- Tracking individual case wise countries where submission is due instead of country wise case submissions

Our approach to flexible Submission Management 'System'

- Allowing different project product details (Marketing authorization) selection while submitting ICSRs
- Option to select appropriate project details based on either Submission country, AE origin country or Source country to suit client's submission conventions
- Allow submission to all/multiple EVHUMAN countries, have submission details uploaded just once; thus saving time and user effort
- Submission compliance ensured for atypical scenarios faced by end-users
- Customized submission rules configured in system where user is alerted of ICSR reportability criteria immediately once case is created in system
- Each user workflow can expedite case(s) as countries where case is eligible for submission is accessible
- Submission rules can be updated from time to time for continued compliance

- Submission compliance report to track for all submissions including delayed submissions, if any!
- Automates versioning & other info. based on previous submissions to each of the applicable countries
- Ignored submission reports can be checked within case/ADR lifecycle for user reference and action
- Generate already submitted reports (CIOMS, XML, VAERS etc.) for sharing, review, archival etc.



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

Electronic batch recording system: process-xe.sarjen.com

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